UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No.1456 Master File No. 01-CV-12257-PBS Subcategory No. 06-CV-11337-PBS
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al.*, Civil Action No. 07-10248-PBS	Magistrate Judge Marianne B. Bowler Master Docket No. 6207

UNITED STATES' RESPONSE TO THE ROXANE DEFENDANTS' STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

The United States submits this response to the Roxane Defendants' Local Rule 56.1 Statement of Undisputed Material Facts in Support of Their Motion for Summary Judgment. To the extent statement of fact asserted by the Roxane Defendants is undisputed, it is undisputed solely for the purposes of the Roxane Defendants' motion for partial summary judgment, and the Plaintiffs reserve the right to dispute any statement in future proceedings.

I. INFORMATION AVAILABLE TO THE GOVERNMENT REGARDING THE DIFFERENCE BETWEEN AWP AND ACTUAL ACQUISITION COSTS: 1980 –1989

1. In 1984, the Office of Inspector General ("OIG") reported that pharmacies could purchase drugs at widespread discounts off of AWP, including as much as 41.8% below AWP (which translates to a 72% spread under Plaintiffs' methodology for calculating spread). (Tab 71, Helms Ex. 5, OIG July 1984, *Changes to the Medicaid Prescription Drug Program Could Save Millions*, at 4, 10 (July 1984 OIG Report).) The OIG's recommendations to HCFA included the following: (1) that HCFA revise its policy and regulations to provide more oversight over Medicaid drug reimbursement, including insertion of "language that will preclude the general use of AWP as the State agencies' 'best estimate of prices providers generally are paying for drugs'"; and (2) that HCFA "[w]ork with State agencies in developing alternative drug reimbursement methodologies which more closely approximate the prices pharmacies pay for drugs." (*Id.* at 23.) The OIG's report was based on its ongoing review of prices at which the nations' wholesalers resold drugs to pharmacies. (*Id.* at 2, 11.) In its report, the OIG stated and concluded the following:

- Because of AWP reimbursement, "[e]xcessive payments are being made nationwide for the ingredient cost of prescription drugs under the Medicaid program." (*Id.* at 3.)
- "The use of AWP in determining Medicaid reimbursement for drugs has been a problem that HCFA has recognized for some time." (*Id.*)
- "HCFA believed that published AWP was too high and, therefore, the purpose of the EAC requirement in the regulations was to move states away from using AWP as the upper limit for reimbursing drug ingredient cost. (*Id.* at 3, 22.)
- "Our review . . . showed that pharmacies rarely purchased the sample drugs at the published AWP. . . . Most of the purchases – 3,455 (99.6 percent) – were made at prices averaging about 16 percent below AWP. These drug purchases ranged from as little as .23

percent below AWP to as much as 42 percent below AWP." (*Id.* at 4.)

- "Our examination of 1,127 direct purchase invoices showed that prices to pharmacies averaged 21.2 percent below AWP; ranging from as little as 6.3 percent below AWP to as much as 41.8 below AWP." (*Id.* at 10.)

- "The use of AWP as an upper limit for Medicaid drug reimbursements is a nationwide problem which is resulting in significant unnecessary program expenditures." (*Id.* at 15.)

- On average, pharmacies purchased drugs for 15.96 percent below AWP. (*Id.* at 15.)

- "[W]e believe that as much as $128 million ($72 million Federal share) in Medicaid expenditures could be saved annually if program policy and regulations were revised so as to require States to abandon the AWP reimbursement methodology in favor of drug pricing systems which would more closely estimate the prices pharmacies generally pay for drugs." (*Id.* at 16.)

- "[P]harmacies do not purchase drugs at the AWP published in the 'Bluebook,' 'Redbook,' or similar publications. Thus, AWP cannot be the best—or even an adequate—estimate of the prices providers generally are paying for drugs. AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, end-of-year discounts and any other trade discounts, rebates, or free goods that do not appear on the pharmacists' invoices." (*Id.* at 22.)

- "The revised regulations should eliminate the use of AWP and require State Medicaid agencies to aggressively pursue alternative methods for establishing upper reimbursement limits." (*Id.*)

- "[O]ur report demonstrates on a nationwide basis that pharmacies are purchasing drugs at prices considerably below published AWP. Thus, AWP is not an adequate estimate of the prices providers generally are paying for drugs." (*Id.* at 24.)

- "[O]ur report demonstrates that the Medicaid program is currently reimbursing pharmacies amounts for drug ingredient cost that are significantly in excess of the pharmacies' actual costs of the drug ingredients—which is contrary to the intent of the existing Federal regulations." (*Id.* at 25.)

United States' Response: The United States does not dispute that in 1984 the Office of Inspector General published a report entitled, *Changes to the Medicaid Prescription Drug Program Could Save Millions.* Roxane has correctly, but selectively, quoted excerpts from that

report; the entirety of the report referenced is the best evidence of its contents. The United States does not dispute that in 1984 pharmacies could buy drugs at discounts from AWP. The United States disputes the materiality of the report to Roxane's liability under the FCA, however. First, the report does not mention Roxane or refer to any of the drugs at issue in this litigation (the "Subject Drugs"). Second, the "spreads" referred to in the report are much smaller than most of those created by Roxane for the Subject Drugs. Third, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Declaration of James J. Fauci in Support of Plaintiff's Motion for Partial Summary Judgment and in Opposition to the Roxane Defendants' Motion for Partial Summary Judgment (hereinafter, "Fauci") Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs; such AWPs were considered by OIG to be "inflated," resulting in Medicare "overpayments." (*See*, *e.g.*, Tab 71 at 1, 9 ("excessive payments are being made" for Medicaid prescription drugs), 15 (use of AWP is "a nationwide problem" resulting in "significant unnecessary program expenditures."))

2. In 1987, the Committee on Ways and Means, Subcommittee on Health, House of Representatives—the committee with budgetary oversight over the Medicare and Medicaid programs—heard testimony from the GAO on "Issues Related to Possible Coverage of Outpatient Prescription Drugs Under Medicare." (Tab 72, June 2, 1987, Testimony of Michael Zimmerman, *Issues Related to Possible Coverage of Outpatient Prescription Drugs Under Medicare*, Subcommittee on Health, Committee on Ways and Means, House of Representatives, GAO/T-HRD-87-15.) In that hearing, Michael Zimmerman, Senior Associate Director, Human Resources Division, testified as follows:

- The AWPs contained in Red Book and Blue Book "do not reflect many types of discounts and rebates available to pharmacies and, thus, tend to overstate pharmacies' drug costs." (*Id.* at 3.)

- "In the mid-1970's, the Department of Health and Human Services (HHS) estimated that AWPs overstated actual costs by 15 to 18 percent." (*Id.*)

- "In the final analysis, the question of how much to pay for a drug comes down to the degree of assurance desired that the pharmacy is not overcompensated and that the program does not pay for expensive brand name drugs when therapeutically equivalent generics are available. The better the estimate of what the pharmacy pays for a drug, the more assurance the pharmacy is not overpaid. And the more incentives to dispense lower cost drugs, or only paying the price of lower cost drugs, the more assurance that high priced drugs are not paid for when equivalent, lower cost ones are available." (*Id.* at 4.)

United States' Response: The United States does not dispute that in 1987 the Committee on Ways & Means, Sub-committee on Health, House of Representatives heard testimony from the GAO on "Issues Related to the Possible Coverage of Outpatient Prescription Drugs Under Medicare." Roxane has correctly, but selectively, quoted excerpts from that testimony; the entirety of the testimony referenced is the best evidence of its contents. The United States does not dispute that pharmacies could buy drugs at a discount from AWP. The United States disputes the materiality of the testimony to Roxane's liability under the FCA, however. First, the testimony did not mention Roxane or refer to any of the Subject Drugs. Second, the "spreads" referred to in the testimony are much smaller than most of those created by Roxane for the Subject Drugs. Third, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any testimony published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/8/2008 Judith Waterer 30((b) (6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, language in the testimony itself indicates disapproval of AWPs that exceeded

providers' actual acquisition costs. (*See*, *e.g.* Tab 72, at page 3, referring to the difficulty of estimating the pharmacy's costs "to preclude overcompensating the pharmacy," and the "problem" of published AWPs exceeding actual costs)

3. On July 5, 1987, the Kentucky-based *Lexington Herald-Leader* published a front-page story entitled "Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars." (Tab 73, Lockwood Ery 15 at 1, July 5, 1987, John Winn Miller, "Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars, *Lexington Herald-Leader*, at A1.) The article included the following-information:

- A pharmaceutical representative and a Pennsylvania Medicaid official told the *Herald-Leader* that "(Average Wholesale Price) is a joke," and AWP "just doesn't mean anything. It has no connection to what pharmacists really purchase the drug for." (*Id.* at 3.)

- "Medicaid programs across the country are making millions of dollars in overpayments because of flaws and abuses in the way they buy prescription drugs for the poor, according to government and industry officials." (*Id.* at 1.)

- Manufacturers use a "sales technique called 'playing the spread.'" A large "spread, or difference, between the [AWP] and the actual price" meant that "a pharmacist buying that drug could make a larger profit." (*Id.* at 4-5.)

- Some "companies actually advertised that they had a better spread" and "many companies routinely list Average Wholesale Prices and 'your price' in their catalogs to show the spread." (*Id.* at 5.)

- Kentucky Medicaid officials discovered that one drug was listed "in the 1987 Red Book as having an Average Wholesale Price of 16.69 cents for each 260 mg. tablet," but the drug "was being sold to pharmacies for only 8.88 cents a tablet – 47 percent below the published Average Wholesale Price." (*Id.* at 4.) Under Plaintiffs' methodology, this is an 88% spread.

- The Government was aware of the issue, but previous attempts to change the system had "met bitter resistance" from pharmacists and other groups, which had forced HCFA to back down from making changes. (*Id.* at 8-9.)

- The National Association of Retail Druggists "led the fight to force the federal Health Care Financing Administration . . . to retreat from proposed changes in 1985 that came up after the inspector general's audit discovered the overpayments." (*Id.*)

- According to the Vice President for Communications of the National Association of Retail Druggists, the Association "'put a lot of pressure on the Health Care Financing Administration, and they backed off." (*Id.* at 3, 9.)

United States' Response: The United States does not dispute that on July 5, 1987, the *Lexington Herald-Leader* published an article *"Drug Industry Over Charging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars*." Roxane has paraphrased and in other instances selectively quoted from that article; the entirety of the article referenced is the best evidence of its content. The United States notes the article is and contains hearsay. The United States does not dispute that in 1987 pharmacies could purchase drugs at a discount from AWP. The United States disputes the materiality of the article to Roxane's liability under the FCA, however. First, the article does not mention Roxane or refer to any of the Subject Drugs. Second, the "spreads" referred to in the article are much smaller than most of those created by Roxane for the Subject Drugs. Third, there is no evidence that responsible officials in Roxane's marketing department ever read such articles or the "federal studies" reported on, and admitted that they did not rely on such information in setting prices for Roxane drugs. (*See, e.g.*, Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 141:10 - 141:22) Finally, language in the article itself indicates government disapproval of AWPs that exceeded providers' actual acquisition costs; such AWPs were considered to be "inflated," resulting in Medicare "overpayments." *(See*, *e.g.*, Tab 73 at 1 (referring to "millions of dollars in overpayments because of flaws and abuses"))

4. In February 1989, the *Philadelphia Inquirer* published an article entitled "When Drugstores Tell You No." (Tab 74, Feb. 12, 1989, Barbara Demick, "When Drugstores Tell You No," *Phila. Inquirer* at G01.) The article included the following information:

- "In a recent study . . . it was found that drugstores actually pay 15 percent less than

average wholesale price for brand-name prescription drugs and up to 50 percent less for generics." (*Id.*) Under Plaintiffs' methodology, this is a 100% spread.

United States' Response: The United States does not dispute that in February 1989 the *Philadelphia Inquirer* published an article entitled, *"When Drug Stores Tell You No."* Roxane has selectively quoted from that article; the entirety of the article referenced is the best evidence of its contents. The United States notes the article is and contains hearsay. The United States does not dispute that in 1989 pharmacies could purchase drugs at a discount from AWP. The United States disputes the materiality of the article to Roxane's liability under the FCA, however. First, the quoted sentence from the article refers to "a recent study commissioned by Mack Trucks." The article itself does not refer to any government study, nor mention Roxane or refer to any of the Subject Drugs. Second, the "spreads" referred to in the article are much smaller than most of those created by Roxane for the Subject Drugs. Third, there is no evidence that responsible officials in Roxane's marketing department read or relied on the article as approval of Roxane's price reporting practices.

5. In February 1989, *Newsday* published an article entitled "No Rx for Plans; Drug Plans Draw Pharmacists' Ire." (Tab 75, Feb. 24, 1989, Elizabeth Sanger, "No Rx for Plans; Drug Plans Draw Pharmacists' Ire," *Newsday* (New York), at 47.) The article included the following information:

- "While drug stores maintain they can't make money on a discounted average wholesale price, insurers say the average wholesale price isn't the price they pay for drugs. Depending on the medicine, the acquisition price can be as much as 50 percent less than the average wholesale price." (*Id.*)

United States' Response: The United States does not dispute that in February 1989 Newsday published an article *"No Rx for Plans, Drug Plans Draw Pharmacists' Ire."* Roxane has selectively quoted from that article; the entirety of the article referenced is the best evidence of its

contents. The United States notes the article is and contains hearsay. The United States does not dispute that in 1989 pharmacies could purchase drugs at a discount from AWP. The United States disputes the materiality of the article to Roxane's liability under the FCA, however. First, the quoted sentence from the article appears to refer to information provided to the reporter by a regional President of CIGNA Health Plans. The article itself does not refer to any government study, nor mention Roxane or refer to any of the Subject Drugs. Moreover, the "spreads" referred to in the article are much smaller than most of those created by Roxane for the Subject Drugs. Finally, there is no evidence that responsible officials in Roxane's marketing department read or relied on the article as approval of Roxane's price reporting practices.

6. In March 1989, the *Arkansas Democrat-Gazette* published an article entitled "Pharmacists Face Big Losses Under Proposal, Official Says." (Tab 76, Mar. 23, 1989, "Pharmacists Face Big Losses Under Proposal, Official Says," *Arkansas Democrat-Gazette*.) The article included the following information:

- HCFA "recently ruled that the average wholesale price [was] no longer an acceptable reimbursement standard." (*Id.* at 1.)
- "Bill McCutcheon of Dallas, deputy regional administrator of the Health Care Finance Administration, said numerous studies and 'open admission by the people who publish those prices' has shown that the average wholesale price 'doesn't represent the actual cost' to pharmacies 'by any stretch of the imagination.' Druggists actually pay less, he said." (*Id.*)

United States' Response: The United States does not dispute that in March 1989 the *Arkansas Democrat Gazette* published an article headlined, "*Pharmacists Face Big Losses Under Proposal, Official Says*." Roxane has selectively quoted from that article; the entirety of the article referenced is the best evidence of its contents. The United States notes the article is and contains hearsay. The United States does not dispute that in 1989 pharmacies could purchase drugs at a discount from AWP. The United States disputes the materiality of the article to

Roxane's liability under the FCA, however. The article itself does not mention Roxane or refer to any of the Subject Drugs. Moreover, there is no evidence that responsible officials in Roxane's marketing department read or relied on the article as approval of Roxane's price reporting practices.

7. In April 1989, the *Washington Post* published an article entitled "Prescription Drug Plans Face Threat; Pharmacy Chains Dropping Programs." (Tab 77, April 14, 1989, Lena H. Sun, "Prescription Drug Plans Face Threat; Pharmacy Chains Dropping Programs," *The Washington Post*, at A1.) The article included the following information:

- "The generally accepted practice in the industry has been to use 'the average whole price'—something akin to the 'blue book' value of an automobile—as a way to measure the cost of the drug." (*Id.* at 2.)

- "A study commissioned by Mack Trucks . . . found that drugstores purchased many individual brand-name prescription drugs for 15 percent less than the average wholesale price, and paid as much as 50 percent less for generic drugs." (*Id.*) Under Plaintiffs' methodology, this is a 100% spread.

United States' Response: The United States does not dispute that in April 1989 the *Washington Post* published an article entitled "*Prescription Drug Plans Face Threat: Pharmacy Claims Dropping Programs."* Roxane has selectively quoted from that article; the entirety of the article referenced is the best evidence of its contents. The United States notes the article is and contains hearsay. The United States does not dispute that in 1989 pharmacies could purchase drugs at a discount from AWP. The United States disputes the materiality of the article to Roxane's liability under the FCA, however. The quoted excerpt from the article refers to "a study commissioned by Mack Trucks." The article itself does not refer to any government study, nor mention Roxane or refer to any of the Subject Drugs. Moreover, there is no evidence that responsible officials in Roxane's marketing department read or relied on the article as approval of Roxane's price reporting practices.

8. In May 1989, *Drug Store News* published an article entitled "AWPs Are a Joke, But No One Is Laughing." (Tab 78, May 1, 1989, Harold Cohen, *AWPs Are a Joke, But No One Is Laughing*, Drug Store News.) The article included the following information:

- "In many instances, AWP actually stands for the highest price at which manufacturers sell their product. If, in fact, a true AWP was assigned to a product, taking into consideration all the various pricing schedules available from drug manufacturers, the AWP would be a much lower number than is normally used." (*Id.*)

- "AWP is being manipulated by many pharmaceutical manufacturers, both generic and branded, to get their products on state, federal and third-party formularies. The feeling is 'Give the pharmacists a higher AWP and they will use or substitute the product with the best AWP to receive a higher rate of reimbursement.'" (*Id*.)

- "Let's face it . . . AWP is a joke, and the folks who run third-party programs are finally recognizing it for what it is, an easy target. I cannot support efforts afoot by segments of the retail pharmacy industry to keep profits made off of phony AWPs by calling them 'earned discounts.'" (*Id.*)

- "[T]he AWP issue may become a moot point once retail pharmacy feels the full impact of the Medicare Catastrophic Drug Act in 1991. According to the law, the AWP is to be determined by the Secretary of Health and Human Services. Once the AWP is in government's hands it will never be the same. It will be scrutinized and uncovered for what it is—a sham. Today's AWP doesn't stand for 'Average Wholesale Price' anymore; it really means 'Against the Working Pharmacist.'" (*Id.*)

United States' Response: The United States questions the authenticity of the purported May 1989 *Drug Store News* article entitled *"AWPs Are A Joke, But No One Is Laughing"* at Tab 78. There is a reference on the page to "stimulus spending," and to an "Obama" proposal for "more health care savings." Authentic or not, the entirety of the article referenced is the best evidence of its contents; Roxane has selectively quoted from the article. The United States notes the article is and contains hearsay. The United States does not dispute that in 1989 pharmacies could purchase drugs at a discount from AWP. The United States disputes the materiality of the article to Roxane's liability under the FCA, in any event. The articles appears to be a health care industry "Email Alert RSS Feed," and does not refer to any government study, nor mention

Roxane or refer to any of the Subject Drugs. Moreover, there is no evidence that responsible officials in Roxane's marketing department read or relied on the article as approval of Roxane's price reporting practices.

9. In July 1989, the United States Senate held a hearing entitled "Skyrocketing Prescription Drug Prices: Are We Getting Our Money's Worth?" (Tab 79, Abbott Ex. 154, July 18, 1989, *Skyrocketing Prescription Drug Prices: Are We Getting Our Money's Worth?: Hearing Before the S. Comm. on Aging*, 101st Cong. (1989).) The hearing included the following testimony:

- Louis B. Hays, Acting HCFA Administrator in charge of Medicaid, testified that "[w]hile the term 'average wholesale price' is suggestive of the amount that pharmacies actually pay for drugs, it is in fact, significantly higher than actual costs. The average wholesale price is somewhat comparable to the manufacturer's sticker price on a new car." (*Id.* at 210, 214 (statement of Louis B. Hays, Acting HCFA Administrator in charge of Medicaid).) "[T]his is rarely the price actually paid for the car." (*Id.* at 214-15.)

- Administrator Hays further testified that "there have been a number of studies which indicate that published average wholesale price for drugs overstates the actual prices paid by as much as 10 to 20 percent, because of discounts, special offers, or purchasing incentives." (*Id.* at 210.)

- Administrator Hays also noted that "[u]nder current law, HCFA has no authority to negotiate more competitive prices or demand the discounts warranted by the large volume of business the Medicare program represents. Indeed, the statute requires us to exclude from the price survey the discounts which pharmacies typically receive from drug companies. Thus, the survey prices will overstate actual pharmacy costs. Multiple source drugs make up the lion's share of the prescription drug market, and, essentially, Medicare will pay the average wholesale price for these drugs." (*Id.* at 214.)

- Veterans Affairs Department Pharmaceutical Products Division Chief Dennis Sytrsky testified that "For multiple-source products . . . the department 'typically' obtains'discounts ranging from 39% to 93%, but most multiple-source drugs in our depots are currently being purchased with discounts of greater than 80%' off AWP." (Tab 80, Abbott Hayashi Ex. 8 at 1, July 24, 1989, "V-A Obtains Rx Drug Price Discounts of 41% for Single Source, 67% for Multisource Drugs not Distributed by Department, Pryor Drug Price Hearing Told," *The Pink Sheet*.) These translate into spreads (under Plaintiffs' methodology) of 64%, 1,328%, and 400%, respectively.

- Senator David Pryor, the Committee Chairman, informed the committee that a bottle of Motrin 800 mg "is priced at $29 to the public—including Medicare—but only $8 to

hospitals and $5 to V-A. The published price (AWP) . . . is $32." (*Id.*)

United States' Response: The United States does not dispute that in July 1989 the United States Senate Committee on Aging held a hearing addressing "*Skyrocketing Prescription Drug Prices: Are We Getting Our Money's Worth?"* Roxane has correctly, but selectively, quoted excerpts of testimony from that hearing; the entirety of the hearing testimony referenced is the best evidence of its contents. The United States does not dispute that in 1989 pharmacies could buy drugs at a discount from AWP. The United States disputes the materiality of the testimony to Roxane's liability under the FCA, however. First, the testimony did not mention Roxane or refer to any of the Subject Drugs. Second, the "spreads" referred to in the testimony are in many instances much smaller than those created by Roxane for the Subject Drugs. Third, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any testimony published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, no language in the testimony itself indicates approval by government officials of reporting of AWPs that exceeded providers' actual acquisition costs, and the Chairman notes at the outset that the Committee would be "unable to adequately pose and ultimately answer" the questions under consideration because only one of the 18 drug manufacturers invited to testify chose to appear to "discuss[] the prices they charge on Main Street." (Tab 81 at 1)

10. Following the hearing, in August 1989, the Senate Committee on Aging authored a report entitled *Prescription Drug Prices: Are We Getting Our Money's Worth?*, Majority Staff Report of the Special Committee on Aging, S. Rep. 101-49, 191st Cong., Aug. 1989 (Tab 81, Aug. 1989 Senate Report).) The report stated and concluded the following:

- Hospitals, HMOs and nursing homes achieved discounts up to 99% off of AWP, which is the equivalent of a 9,900% spread using Plaintiffs' methodology. (*Id*. at 11; *see also* Tab 80, Abbott Hayashi Ex. 8 at 2-3.)

- "There are two markets in the United States for most big-selling prescription drugs: a price-competitive market characterized by deep discounts off the published list price, and a high-priced market, where retail customers, Medicare and Medicaid purchase their prescription drugs." (Aug. 1989 Senate Rep. at 10.)

- The Department of Veterans Affairs received on average a 67% discount off of published AWP for generic drugs, as well as 41% off published AWP for single-source drugs. (*Id*. at 11.)

United States' Response: The United States does not dispute that in August 1989 the Senate Committee on Aging authored a report entitled *Prescription Drug Prices: Are We Getting Our Money's Worth?*" Roxane has correctly, but selectively, quoted excerpts from that report; the entirety of the report referenced is the best evidence of its contents. The United States does not dispute that in 1989 pharmacies could buy drugs at a discount from AWP. The United States disputes the materiality of the report to Roxane's liability under the FCA, however. First, the report did not mention Roxane or refer to any of the Subject Drugs. Second, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, no language in the report indicates approval by government officials of reporting of AWPs that exceeded providers' actual acquisition costs.

11. In September 1989, the OIG reported to HCFA that drugs could be purchased at significant discounts off of AWP, including an average of 18.2% off AWP for generic drugs, (Tab 82, Dey Ex. 46 at 4-5, OIG Sept. 1989, "Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program, A-06-89-

00037, (1989 OIG Report)), which is a 22% spread under Plaintiffs' methodology. The OIG specifically recommended that: (1) the use of AWPs by HCFA in the Medicaid or Medicare programs "should be discontinued" (*id.* at 7); (2) if HCFA decided to continue using AWP for Medicare, AWP should be discounted (*id.*); and (3) in the Medicaid program, HCFA "require State agencies to discount AWP when making program reimbursements." (*Id.*) The report was a continuation of the OIG's 1984 study, which reviewed prices at which the nation's largest wholesalers resold drugs to pharmacies. (*Id.* at 4.) The OIG report also included the following statements and conclusions:

- "[T]he preponderance of the evidence shows that AWP is heavily discounted" and that "AWP overstates the prices as much as 10 to 20 percent." (*Id*. at 1.)

- Between 1984 and 1989, the OIG noted a "much wider base of awareness" of the variances between AWPs and acquisition costs. (*Id*.) All "facets of the industry are willing to admit that . . . discounts [from AWP] exist." (*Id*. at 6.)

- "We continue to believe that AWP is not a meaningful figure, and that it should not be used for making reimbursements in either the Medicaid or the new Medicare drug program." (*Id.* at 1.)

- HCFA should abandon use of AWP for both the Medicaid and Medicare drug programs. (*Id.* at 1, 2, 7.)

- "Concerning Medicare, we are recommending that HCFA study the feasibility of other reimbursement methods that do not involve AWP and seek legislative changes to permit either the use of a different method or the discounting of AWP." (*Id*. at 2.)

- On average, pharmacies bought drugs for 15.5 percent below AWP. (*Id*. at 1, 4.) For single-source drugs, the average discount off AWP was 14.39 percent. (*Id.* at 4.) Multi-source drugs had a weighted average price below AWP of 18.2 percent. (*Id.*)

- "[W]e continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or Medicare programs. When AWP is used, we believe that it should be discounted." (*Id*. at 7.)

- Several wholesalers made the following representations to OIG:

  • "AWP is a meaningless figure." (*Id.* at 5.)

  • "[I]t is recognized in the industry that there are discounts off AWP . . . selling price is based on AWP less a discount or . . . cost plus a markup." (*Id.*)

- OIG also noted quotes from the 1989 *Lexington Herald-Leader* article:

• "The (Average Wholesale Price) is a joke . . . it has largely become a farce because many companies have abused it and continue to abuse it." (*Id.* at 6.)

• AWP "just doesn't mean anything. It has no connection to what pharmacies really purchase the drug for." (*Id.*)

United States' Response: The United States does not dispute that in September 1989 the OIG issued a report entitled *Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program*. Roxane has correctly, but selectively, quoted excerpts from that report; the entirety of the report referenced is the best evidence of its contents. The United States does not dispute that in 1989 pharmacies could buy drugs at discounts from AWP. The United States disputes the materiality of the report to Roxane's liability under the FCA, however. First, the report does not mention Roxane or refer to any of the Subject Drugs. Second, the "spreads" referred to in the report are much smaller than most of those created by Roxane for the Subject Drugs. Third, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs. (*See*, *e.g.*, Tab 82, at 7 (recommending "a legislative change" for the Medicare program "to either use a different reimbursement method or to discount AWP"))

II. GOVERNMENT POLICY DECISIONS TO MAINTAIN AWP AND NOT USE ACTUAL ACQUISITION COST AS THE BASIS FOR REIMBURSEMENT: 1980 – 1991

12. In July 1987, HCFA established the FUL program for multisource drugs. (*See* Tab 83,

Abbott Ex. 284, Medicare and Medicaid Programs; Limits on Payments for Drugs, 52 Fed. Reg. 28648 (July 31, 1987).) Rather than adopting a formula based on actual acquisition costs, HCFA capped reimbursement at 150 percent of the lowest published price. HCFA also encouraged states to allow pharmacies to retain profits on generic drug purchases:

- HCFA encouraged "State agencies [to] be innovative in these programs and find ways to assure the availability at reasonable prices of multiple-source drugs. One way they could do this would be to encourage retail pharmacy participation in the Medicaid program by permitting them to retain profits from the sale of listed drugs to Medicaid recipients." (*Id.* at 28653.)

- "In the previous section, we discussed the possible effects of building into our rates for ingredients a profit margin for pharmacists. We expressed the hope that States would recognize the advantage of providing pharmacists with an incentive to participate in the Medicaid program and to stimulate pharmacists to engage in prudent purchasing practices and the substitution of lower cost therapeutically equivalent products." (*Id.* at 28656.)

- HCFA's choice of a 150 percent markup was made "in order to meet the following two objectives: (1) That the markup be high enough to assure that pharmacists can normally obtain and stock an equivalent product without losing money on acquisition costs of incurring the expense of departure from normal purchasing channels, and (2) that the markup not be so high as to cost the Medicaid program unnecessary money." (*Id.* at 28653.)

United States' Response: The United States does not dispute that in July 1987 HCFA published the final rule at 52 Fed. Reg 28,648 which relates to the FUL. Roxane has selectively quoted from 52 Fed. Reg. 28,648. The United States disputes the materiality of the rule to Roxane's liability under the FCA. There is no evidence that responsible officials in Roxane's marketing department relied on this regulation in setting AWPs, or that Roxane considered it an indication that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 158 - 159, 160:10 - 160:22, 161-162; 166:6 - 166:22, 167:1 - 167:14)

13. Based primarily on the July 1984 OIG Report, in August 1989, HCFA issued a revision to the State Medicaid Manual, which acknowledged the following as to brand name drugs and drugs other than multiple source drugs:

- "[T]here is a preponderance of evidence that demonstrates that such AWP levels overstate the prices that pharmacists actually pay for drug products by as much as 10-20 percent because they do not reflect discounts, premiums, special offers or incentives, etc. Consequently, absent valid documentation to the contrary, a published AWP level as a State determination of EAC without a significant discount being applied is not an acceptable estimate of prices generally and currently paid by providers." (Tab 84, Marmor Ex. 16, HCFA Payment for Services § 6305.1.B, 1989 Revisions at 6-72; 1989 OIG Report at 1-2.)

United States' Response: The United States does not dispute that in August 1989 HCFA issued a revision to the State Medicaid Manual, § 6305.1. The revision does not state it was based primarily on the July 1984 OIG report. Further, the conclusion in the Medicaid Manual was predicated not upon the OIG report, but rather on "a number of" unidentified studies. Roxane has correctly, but selectively, quoted excerpts from that publication; the entirety of the Manual referenced is the best evidence of its contents. The United States does not dispute that in 1989 pharmacies could buy drugs at discounts from AWP. The United States disputes the materiality of the Manual to Roxane's liability under the FCA, however. First, it does not mention Roxane or refer to any of the Subject Drugs. Second, the 10-20% "spreads" referred to in the report are much smaller than most of those created by Roxane for the Subject Drugs. Third, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, no language in the Manual indicates approval of AWPs that exceeded providers' actual acquisition costs.,

14. In 1989, HCFA sent a Transmittal Notice to State Medicaid agencies alerting them that "nondiscounted or unmodified AWP is not acceptable for State use as the basis for estimated acquisition cost (EAC), absent any compelling evidence to the contrary." (Tab 85, Roxane Ex. 121, Jan. 31, 1989 HCFA Transmittal Notice, Region IV, "Use of Nondiscounted Average

Wholesale Price (AWP) as Estimated Acquisition Cost (EAC) in Medicaid Drug Reimbursement.") It added that "HCFA's policy is that there is a preponderance of evidence that indicates that AWP significantly overstates the prices that pharmacists are currently paying for drug products." (*Id.*) HCFA informed the states that if they were using an undiscounted or unmodified AWP, they would be required to "justify their use of AWP with appropriate data." (*Id.*)

United States' Response: The United States does not dispute that in 1989 HCFA sent a "Region IV" transmittal notice to State Medicaid Agencies, "Use of Non-discounted Average Wholesale Price (AWP) as Estimated Acquisition Cost in Medicaid Drug Reimbursement." Roxane has correctly, but selectively, quoted excerpts from that notice; the entirety of the document referenced is the best evidence of its contents. The United States does not dispute that in 1989 pharmacies could buy drugs at discounts from AWP. The United States disputes the materiality of the document to Roxane's liability under the FCA, however. It does not mention Roxane or refer to any of the Subject Drugs. Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any notices or reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18)

15. Citing the findings of the 1984 and 1989 OIG studies, in June 1991, HCFA proposed a reimbursement formula of AWP-15% for Medicare Part B drugs. (Medicare Program; Fee Schedule for Physicians' Services, 56 Fed. Reg. 25792, 25800, 25860 (June 4, 1991) (proposed rule)). HCFA stated that "based on studies by the Office of the Inspector General . . . and other information, we believe that the Red Book and other wholesale price guides substantially overstate the true cost of drugs." (*Id.* at 25800)

United States' Response: The United States does not dispute that in June 1991, HCFA proposed a reimbursement formula of AWP-15% for Medicare Part B drugs in a proposed rule published in the Federal Register at 56 Fed. Reg. 25,792, 25,800, 25860 (June 4, 1991). Roxane

has correctly, but selectively, quoted from 56 Federal Register 25,972. The entirety of the document referenced is the best evidence of its content. The United States does not dispute that in 1991 providers could buy drugs at a discount from AWP. The United States disputes the materiality of the proposed rule to Roxane's liability under the FCA, however. It does not mention Roxane or refer to any of the Subject Drugs. Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any proposed rule or report published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18)

16. Because of provider and access concerns, however, HCFA rejected this proposal and instead, in November 1991, HCFA adopted a rule that reimbursement for Medicare Part B drugs be at the lower of 100% AWP or EAC. (Medicare Program; Fee Schedule for Physicians' Services, 56 Fed. Reg. 59502, 59525 (Nov. 25, 1991 (final rule) (codified at 42 C.F.R. §§ 405.517, 415.36)). Comments received by HCFA in response to the proposed regulations, and HCFA's response thereto, included the following:

- "We received a great many comments on this issue, primarily from oncologists indicating that our 85 percent standard was inappropriate. The thrust of most of the comments was that many drugs could be purchased for considerably less than 85 percent of AWP—particularly multi-source drugs—while others were not discounted. Other commenters suggested that, while pharmacies and perhaps large practices could receive substantial discounts on their drug purchases, individual physicians could not. The bulk of the comments suggesting alternatives to our proposal indicated that the amounts paid should be based on actual or estimated acquisition costs." (*Id.* at 59524.)

- "Response: After considering all of the comments on this issue, we have decided to modify the proposed policy. Payment for drugs would be based on the lower of the national AWP or the Medicare carrier's estimate of actual acquisition costs. Since there can be many wholesale prices listed for each drug because of multiple sources for the drug, we are defining the national AWP as the median price for all sources of the generic form of the drug. Estimated acquisition costs would be based on individual carrier estimates of the costs that physicians, or other providers as appropriate, actually pay for the drugs." (*Id.* at 59525.)

United States' Response: The United States does not dispute that in November 1991 HCFA adopted 56 Fed. Reg. 59,502, 59,525 (Nov. 25, 1991 codified at 42 C.F.R. §405.517, 415.36) The United States disputes Roxane's characterization of HCFA's actions in promulgating this rule.

Roxane has correctly, but selectively, quoted from comments received by HCFA in response to the proposed regulation. The comments in their entirety are the best evidence of their content. The United States does not dispute that in 1991 pharmacies can purchase drugs at discounts from AWP. The United States disputes the materiality of the document to Roxane's liability under the FCA, however. It does not mention Roxane or refer to any of the Subject Drugs. Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any rule or report published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18)

III. ADDITIONAL INFORMATION ESTABLISHING THE DIFFERENCE BETWEEN AWP AND ACTUAL ACQUISITION COSTS: 1990 – 1999

17. In June 1990, *Drug Store News* published an article entitled "There's Nothing 'Average' About AWP." (Tab 86, June 11, 1990, Harold Cohen, "There's Nothing 'Average' About AWP," *Drug Store News*.) The article included the following information:

- "AWP has become an exploited figure that is often picked out of thin air by pharmaceutical manufacturers who know that as long as third-party programs continue to use AWP as a base for reimbursement, the higher the number the better their chances are of getting their product dispensed. But there's nothing average about AWP. . . . The AWP of today is not the same AWP of 25 years ago." (*Id.*)

United States' Response: The United States questions the authenticity of the purported January

1990 *Drug Store News* article entitled "There's Nothing 'Average' About AWP." There is a reference on the page to "Stimulus spending," and to an "Obama" proposal for "more health care savings." Authentic or not, the entirety of the article referenced is the best evidence of its contents; Roxane has selectively quoted from that article. The United States notes the article is and contains hearsay. The United States does not dispute that in 1990 pharmacies could purchase drugs at a discount from AWP. The United States disputes the materiality of the article to Roxane's liability under the FCA, in any event. The articles appears to be a health care industry "Email Alert RSS Feed," and does not refer to any government study, nor mention Roxane or refer to any of the Subject Drugs. Moreover, there is no evidence that responsible officials in Roxane's marketing department read or relied on the article as approval of Roxane's price reporting practices.

18. Thomas A. Scully, senior White House staff member on health care from 1990-91, and HCFA/CMS Administrator from May 2001 through January 2004 (Tab 46, 05-15-07 Scully Dep. 97, 50), understood that AWP was not an actual acquisition cost as early as 1991:

- Since 1990-91, Scully believed that AWP itself was "air"—a "completely contrived number," and that the reimbursement system was "insane." (*Id.* at 194-95, 133-34.)
- Since 1990-91, Scully was aware that hospitals were pocketing revenue and margins from the spread between AWP and acquisition costs. (*Id.* at 44-46.)
- Scully characterized the reimbursement policy, whereby hospitals would, for example, "acquire drugs for . . . 5 or 600 dollars" and get reimbursed by Medicare at "95 percent of average wholesale price, which was frequently 1500 dollars or more," as "insane" and "absurd." (*Id.*)

United States' Response: Roxane has selectively, and in some cases inaccurately, quoted from the testimony of Mr. Scully. Mr. Scully testified that in 1990-1991 he was aware that hospitals were pocketing revenue on the difference between acquisition cost and reimbursement for

Procrit, Aransep and oncology drugs. (Tab 46, at 43:20 - 43:22; 44:1- 44:22, 45:1 - 45:16) These drugs are not at issue in this case. Mr. Scully also testified to his view that manufacturers were "gaming the system." (*Id.*, at 321, 325-329) He did not testify to any formal policy or statement demonstrating government approval of Roxane's price reporting practices, nor to any communication from Roxane in which it explained its practice of reporting AWPs that are not an actual average wholesale price of Roxane drugs. Roxane acknowledges that the federal government never informed Roxane that it approved of Roxane's conduct in reporting inflated AWPs. (Fauci Exhibit 130 (12/12/2008 Judith Waterer Dep.), at 140:15 - 140:22, 141:1 - 141:4, 207:9 - 207:18, 208:1 - 208:6, 217)

19. Between December 1991 and October 1992, the United States General Accounting Office (GAO) conducted a study of nine pharmacies in Illinois and Maryland "to determine the differences between what the pharmacies were reimbursed by Medicaid for outpatient drugs and what they paid." (Tab 87, Abbott Ex. 458 at 3-4, GAO March 18, 1993, *Medicaid: Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland* (1993 GAO Report).) In March 1993, the GAO published the results of its study, revealing that purchase prices for the pharmacies they studied "ranged from 16 to 42 percent less than AWP" (*id.* at 5-6.), which translates to 19 to 72 percent spreads under Plaintiffs' methodology for calculating spread. The study showed that on average, pharmacies "paid an average 26 percent less than AWP for the drugs" (which translates into a spread of 35 percent under Plaintiffs' methodology). (*Id.* at 5.) The report also noted that "HCFA and state Medicaid officials agreed that pharmacies must often use excess Medicaid reimbursements to cover their dispensing costs. However, because the officials did not have current data on dispensing costs, they did not know what dispensing fees should be." (*Id.* at 6.)

United States' Response: The United States does not dispute that in March 1993 the GAO issued a report entitled " Medicaid: Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland," pertaining to reimbursement for the nine pharmacies in Illinois and Maryland referenced at page 4. Roxane has correctly, but selectively, quoted excerpts from that report; the entirety of the report referenced is the best evidence of its contents.

The United States does not dispute that in 1993 pharmacies in Maryland and Illinois could buy drugs at discounts from AWP. The United States disputes the materiality of the report to Roxane's liability under the FCA, however. First, the report does not mention Roxane or refer to any of the Subject Drugs. Second, the "spreads" referred to in the report are smaller than most of those created by Roxane for the Subject Drugs. Third, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, no language in the report itself indicates approval of AWPs that exceeded providers' actual acquisition costs.

20. In January 1994, the GAO conducted an additional study. In a report comparing prices for pharmaceuticals in the United States to prices in the United Kingdom, the GAO noted "Some observers have criticized the use of WAC as a measure of manufacturers' prices because it does not capture manufacturers' discounts and prices to certain customers. However, the WAC is the correct measure for an analysis of the undiscounted segment of the U.S. pharmaceutical market." (Tab 88, GAO Report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives, Prescription Drugs; Companies Typically Charge More In The United States than in the United Kingdom (Jan. 1994) at p. 19, n.16.)

United States' Response: The United States does not dispute that in January 1994, the GAO issued a report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives, entitled *Prescription Drug Companies Typically Charge More in the United States than in the United Kingdom*. Roxane has correctly, but selectively, quoted excerpts from that report; the entirety of the report referenced is the best evidence of its contents. The United States disputes the materiality of the report to Roxane's liability under the FCA. First, the report does not mention Roxane or refer to any of the Subject

Drugs. Moreover, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, no language in the report itself indicates approval of AWPs that exceeded providers' actual acquisition costs.

21. In August 1994, the OIG began conducting a nationwide review of the difference between published AWPs and pharmacies' actual acquisition costs of generic drugs in the Medicaid program, by focusing on a random sample of eleven states. (Tab 7, 06-24-08 Chesser Dep. 66; Tab 89, Roxane Ex. WY 4, OIG Aug. 4, 1997, *Medicaid Pharmacy: Actual Acquisition Cost of Generic Prescription Drug Products*, A-06-97-00011, Aug. 4, 1997 ("Aug. 1997 OIG Report").) Based on the results of the 1994-95 study, in 1997, the OIG informed HCFA that the nationwide average acquisition cost was 42.5% below AWP—a spread of 74%. (Tab 89, Aug. 1997 OIG Report at 4.) The study culminated in a series of state-specific reports published by the OIG and the August 1997 OIG Report. The OIG recommended that HCFA "work to ensure that states reimburse the ingredient portion of Medicaid drugs in a manner more consistent with the findings of this report." (*Id.* at Appendix 3, p. 2.) In its report, the OIG stated and concluded the following:

- Discounts off AWPs for generic drugs were on average 42.5%—the equivalent of a 74% spread under Plaintiffs' methodology. (*Id.* at 4.)

- "An article in the June 10, 1996 issue of *Barron's* entitled, 'Hooked on Drugs,' focused additional attention on AWP and its relationship to actual acquisition cost. *Barron's* compared about 300 dose forms of the top 20 Medicare drugs and concluded that the true cost was 10 to 20 percent below AWP for brand name drugs [(the equivalent of 11 to 25 percent spreads)], and 60 to 85 percent below AWP for generic drugs [(the equivalent of 150 to 567 percent spreads)]. *Barron's* also reported that industry insiders joke that AWP really means 'Ain't What's Paid'." (*Id.* at 1-2 (quoting Barron's at 15-16).)

- "The findings shown in the report confirm the belief shared by many states that the pharmacy's actual generic drug acquisition costs are much less than the prices paid by many states to the pharmacies." (*Id.*, Appendix 3, p. 2.)

United States' Response: The United States does not dispute that on August, 4 1997, the OIG issued a report entitled *Medicaid Pharmacy: Actual Acquisition Cost of Generic Prescription*

Drug Products. Roxane has correctly, but selectively, quoted excerpts from that report; the entirety of the report referenced is the best evidence of its contents. The United States disputes the materiality of the report to Roxane's liability under the FCA, however. First, the report does not mention Roxane or refer to any of the Subject Drugs. Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, no language in the report itself indicates approval of AWPs that exceeded providers' actual acquisition costs.

22. OIG agent Paul Chesser and his colleagues assisted with the 1994 study. Their involvement was as follows:

- In 1994, the OIG identified a random sample of pharmacies in eleven different states. The surveyed pharmacies were classified into categories: chain, independent, or nontraditional. The OIG then asked the states involved in the review to send out a standard letter to those pharmacies. (Tab 7, 06-24-08 Chesser Dep. 156-157; 165; 173-78.)

- They compiled prices from pharmacy invoices to develop a comprehensive, statistically valid measure of the percentage difference between AWP and acquisition cost for virtually all products reimbursed by Medicaid. (Tab 8, 10-28-08 Chesser Dep. 464-469.)

- Mr. Chesser was the contact person for pharmacies participating in the study. As part of that role, he answered questions they had about the study (*id.* at 616) and explained the purpose of the study. (*Id.* at 617.)

United States' Response: The United States does not dispute that Paul Chesser and his colleagues assisted with the 1994 study. Roxane has selectively, and in some cases inaccurately, quoted from the testimony of Mr. Chesser. The United States does not dispute the statements in the first bullet point of 22. The statements in the second and third bullet point are disputed

because inaccurate. For example, the second bullet refers to testimony that refers to a different study. (*See* Tab 7, at 616-617)

23. In November 1994, a publication called *Drug Topics* reported on the HCFA study. (Tab 90, Abbott Ex. 036 11-7-1994, "HCFA Taking Hard Look at Drug Costs," *Drug Topics*.) The article noted that HCFA undertook the study to "develop an estimate of the difference between the actual acquisition cost of [drugs] and the AWP," using data obtained from "48 randomly selected chain and independent pharmacies in 12 randomly selected states." (*Id.*)

United States' Response: The United States does not dispute that the November 7, 1994 Drug Topics contained an item headed "HCFA Taking Hard Look at Drug Costs." Roxane has selectively quoted from that item. The entirety of the item referenced is the best evidence of its content. Further, the item is and contains hearsay. The United States disputes the materiality of the item in "Drug Facts" to Roxane's liability under the FCA. The item does not mention Roxane or the Subject Drugs. Moreover, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any article published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18)

24. One of the surveyed pharmacies was Cobo Pharmacy in Key West, Florida—a pharmacy that is owned and operated by Ven-A-Care's then-president Luis Cobo. (*See* Tab 10, 01-18-08 Cobo Dep. 31-32; 103-06; Tab 11, 03-04-08 Cobo Dep. 390-92; Tab 12, 07-31-08 Cobo Dep. 868-69).

United States' Response: The United States does not dispute that Cobo Pharmacy in Key West, Florida, a pharmacy then owned and operated by Luis Cobo who was then President of Ven-A-Care, participated in an OIG survey in or around 1994.

25. Bruce Vladeck, Ph.D. was the HCFA Administrator from May 1993 to September 1997 (Tab 59, 05-04-07 Vladeck Dep. 77-78). The HCFA Administrator is responsible for

supervising, and is the "top person running, day-to-day, both the Medicare and Medicaid programs." (*Id.* 95; Tab 60, 06-21-07 Vladeck Dep. 393.) He/she reports to the Secretary of the Department of Health and Human Services, who reports directly to the President of the United States; therefore, the HCFA Administrator is only two steps removed from the President. (Tab 60, 06-21-07 Vladeck Dep. 392-95.)

United States' Response: The United States does not dispute the statements in paragraph 25 except to the extent it characterizes the testimony that the HCFA Administrator is essentially only two steps removed from the President. The United States disputes the materiality of the statements contained in this paragraph.

26. Administrator Vladeck testified that he was aware that AWP was not an actual acquisition cost, and, by the end of his term in 1997, was aware of average discounts for generic drugs of 42.5%, which is a 74% spread under Plaintiff's methodology. (Tab 59, 05-04-07 Vladeck Dep. 213-17; Tab 60, 06-21-07 Vladeck Dep. 497-98; Tab 59, 05-04-07 Vladeck Dep. 229-30.)

- "We did not believe we were paying actual acquisition costs." (Tab 60, 06-21-07 Vladeck Dep. 382.)
- HCFA "knew all along we were overpaying for drugs in the Medicare program" and had information regarding mega-spreads exceeding "500 percent, and in some instances more than 1,000 percent." (*Id.* at 526-27.)
- "[I]n fact, the expectation, the belief about generics, was that it was more likely to be between 25 and 40 percent difference between actual market price and average wholesale price"—an equivalent of 33 and 67 percent spreads, respectively, according to Plaintiffs' formula. (*Id.* at 497-98.)
- By 1997, Vladeck was aware that average discounts for generic drugs were 42.5 percent below AWP, which translates into a spread of 74%. (Tab 59, 05-04-07 Vladeck Dep. 229-30; Tab 60, 06-21-07 Vladeck Dep. 497-98.)

United States' Response: The United States disputes the statements in this paragraph. Mr. Vladeck testified that he did not specifically recall being advised of a 42.5% variation from AWP for generic drugs (Tab 59, at 216-217) and that he didn't "recall being focused on this issue very much at all at the very end of my tenure," but that "since 2003 I've been aware of the difference

in average discounting of generic and brand name drugs; but whether or not I was at the time, I can't say." (*Id.,* at 218) Further, the cited testimony does not refer to spreads. Roxane's paraphrasing of selective excerpts further misquotes the testimony referred to: "If she [Ms. Buto] gave credence to the letter" from VAC "but I would hasten to suggest that was irrelevant to our considerations. We already had proposals pending to change the way in which we paid for these drugs. And the specific amount of — by which we were over paying was not a very important consideration." Of profit margins of 1000%, he stated "I don't know what you mean by on notice. I think that it is fair to say we knew all along we were overpaying for drugs in the Medicare program, which is why we kept trying to change the way we paid for them." (Tab 60, at 529:2 - 529:6.) Further, Dr. Vladeck testified that he believed reported AWPs bore a predictable` relationship to sales prices. (Fauci Exhibit 177 (5/4/07 Bruce Vladeck Dep.) at 138:21- 140:6, 154:4 - 154:21, 156)

27. In January 1996, the Congressional Budget Office ("CBO") published a report that found that "wholesalers paid on average 80 percent of the [AWP]" for the top-selling Medicaid drugs in 1993. (Tab 91, Dey Ex. 173A at 20, Box 2, Jan. 1996 Congressional Budget Office, *How The Medicaid Rebate On Prescription Drugs Affects Pricing In The Pharmaceutical Industry* (Jan. 1996 CBO Report).) Using AMPs collected by HCFA and AWPs reported in *Redbook*, the Congressional Budget Office compared the relationship between the two figures "to determine the equivalent discount off the AWP that a private purchaser must obtain before the Medicaid best-price provision applies." (*Id.*) The CBO made the following statements and conclusions:

- "The average wholesale price (AWP) is the published (list) price that manufacturers suggest wholesalers charge their customers. Wholesalers usually charge pharmacists a price that is lower than the AWP, which is the price that is most widely available in published form." (*Id.*)

- "[T]he average manufacturer price (AMP), used to calculate the Medicaid rebate, is not public information. The AMP is lower than the AWP since it is the average price paid by wholesalers." (*Id.*)

- "CBO examined the relationship between the AWP and AMP for 224 drug products that were the top-selling Medicaid drugs in 1993 (based on data collected by the Health Care Financing Administration for the Medicaid rebate program and the AWPs reported in Redbook). For that sample, the AMP averaged 80 percent of the AWP. Therefore, wholesalers paid on average 80 percent of the list price for those drugs. For 84 percent of the 224 drug products examined, the AMP fell between 75 percent and 85 percent of the AWP. For 94 percent of the 224 drug products, the AMP fell between 75 percent and 90 percent of the AWP. Given that the AMP is equal to 80 percent of the AWP on average, a discount of 32 percent off the AWP equals a discount of 15 percent off the AMP on average." (*Id.*)

United States' Response: The United States does not dispute that in January 1996 the Congressional Budget Office published *How the Medicaid Rebate on Prescription Drugs Affects Pricing In The Pharmaceutical Industry*. Roxane has selectively quoted excerpts from that report; the entirety of the report referenced is the best evidence of its content. The United States disputes the materiality of the report. Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18)

28. At a February 27, 1996 hearing, Representative Pete Stark of California, the ranking member of the House of Representatives Ways and Means Subcommittee on Health introduced a bill seeking to stop fraud and waste in Medicare payments. In support of the bill, Rep. Stark stated the following:

- "Medicare [is] being defrauded by pharmaceutical companies . . . because AWP . . . is grossly overstating the true price of these drugs to health care providers. . . . The AWP figures reported in such sources as *Drug Topics Red Book, American Druggist Blue Book*, or *Medispan* are simply not reflective of what the reimbursed price should be." (Tab 92, Roxane Ex. 30, Feb. 27, 1996, Statement of Congressman Pete Stark in the House of Representatives at 1.)

United States' Response: This United States does not dispute that at a February 27, 1996,

hearing Representative Pete Stark, ranking member of the House of Representatives Ways and Means Committee, introduced a bill to stop fraud and waste in Medicare pharmaceutical payments; the bill referred specifically to oral anti-cancer drugs, which are not at issue in this case. Roxane has selectively quoted from a statement by Congressman Stark in support of that bill. The entirety of the statement referenced is the best evidence of its content. The United States disputes the materiality of the floor statement on a proposed bill, since Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any government statements published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18)

29. In its May 1996 report, titled "Appropriateness of Medicare Prescription Drug Allowances," the OIG informed HCFA that Medicare could have saved $144 million in 1994 if it had used reimbursement formulas more similar to those used in Medicaid instead of an undiscounted AWP. (Tab 94, Dey Ex. 8, OIG May 1996, "Appropriateness of Medicare Prescription Drug Allowances," OEI-03-95-00420 ("May 1996 OIG Report").) The OIG also suggested that HCFA could reimburse drugs based on actual acquisition cost. (*Id.* at 11.)

United States' Response: The United States does not dispute that in May 1996 the OIG issued a report entitled "Appropriateness of Medicare Prescription Drug Allowances." Roxane has selectively quoted excerpts from that report. The entirety of the report referenced is the best evidence of its content. The United States does not dispute that pharmacies could purchase pharmaceuticals at a discount from AWP. The United States disputes the materiality of the report to Roxane's liability under the FCA, however. First, the report does not mention Roxane or refer to any of the Subject Drugs. Second, the "spreads" referred to in the report are smaller than most of those created by Roxane for the Subject Drugs. Third, Roxane's 30(b)(6) designee

testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs; such AWPs were considered to be "inflated," resulting in excessive or "overpayments." (*See*, *e.g.*, Tab 94, at ii (Medicare allowances "may not be appropriate"))

30. In June 1996, *Barron's* published an article entitled "Hooked on Drugs." The article indicated that AWP was not an actual acquisition cost:

- Reported prices for "the top 20 Medicare drugs (which account for about 75% of the program's drug spending), as well as for various intravenous solutions." (Tab 95, Hartman Ex. 7, June 10, 1996, Bill Alpert, "Hooked on Drugs," *Barron's* at 15.)
- AWP "really means 'Ain't What's Paid.'" (*Id.*)
- "[D]rug providers actually pay wholesale prices that are 60-90% below the so-called average wholesale price, or AWP, used in reimbursement claims"—the equivalent of 150-900% spreads. (*Id.*)
- AWPs "originate with the manufacturer" and "for generic drugs, nearly every manufacturer's price was 60-85% below the published [AWP]," the equivalent of 150-567% spreads, respectively. (*Id.* at 15-16.)
- "[D]rug salespeople . . . let[] the doctor know that his product has a bigger spread between AWP and the real price than any other generic firm." (*Id.* at 16.)
- "If manufacturers deliberately maintain lofty AWPs on their generic drugs . . . the drug makers might then gain market share and higher sales from their customers' over-utilization" (*Id.*)
- "Some of these AWP's actually have risen, while real wholesale prices have plummeted." (*Id.*)
- Medicare and Medicaid "have been paying too much for . . . drugs" because they "generally use AWP as a benchmark for reimbursement." (*Id.* at 16-17.)

United States' Response: The United States does not dispute that in June 1996 *Barron's* published an article entitled "Hooked on Drugs." Roxane has selectively quoted excerpts from the article. The entirety of the article referenced is the best evidence of its content. This article contains hearsay. The United States does not dispute that pharmacies can purchase drugs at discounts from AWPs. The United States disputes the materiality of the article in any event. The article does not mention Roxane or the Subject Drugs. Moreover, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any article published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18)

31. The *Barron's* article also included quotations and statements indicating that the alleged conduct is fraudulent, and implicates the Anti-Kickback statute and the False Claims Act:

- "[T]he Justice Department is serving 'civil investigative demands' – a kind of subpoena in antitrust investigations – on manufacturers, asking how those inaccurate AWPs wind up in the *Red Book* and *Blue Book*." (*Id.* at 18.)
- An investigator stated that the "drug makers created false statements so that the doctors could make hundreds of millions of dollars" and that "if OIG doesn't get them, the Justice Department will." (*Id.*)
- "Some investigators view the spreads guaranteed by extreme average wholesale prices as a kind of kickback to doctors, in violation of federal laws." (*Id.*)
- "One group of infusion-industry veterans is reportedly considering attacking the problem by filing a private suit under the False Claims Act." (*Id.*)

United States' Response: The United States does not dispute the publication of the article or its contents. Roxane has selectively quoted excerpts from the Barron's article; the entirety of the article referenced is the best evidence of its content. The United States disputes the materiality of

the article to Roxane's purported defenses. Far from evidencing government approval, the article itself shows that investigators interviewed for the article believed the reporting of inflated AWPs to be false, if not illegal, conduct.

32. By 1997, the OIG knew that Ven-A-Care was alleging a massive fraud on the Medicaid system. (Tab 57, 02-06-08 Vito Dep. 1224-26.)

United States' Response: Disputed. Mr. Vito testified that he knew of Ven-A-Care's allegations. Mr. Vito is not the OIG. (Tab 157, at 1223-1226) In any event, Mr. Vito's testimony did not indicate OIG or other government approval of Roxane's reporting of inflated AWPs for the Subject Drugs.

33. In January 1997, the *Washington Post* reported that "AWP is not . . . the price that's really charged most customers." (Tab 96, Abbott Ex. 239, Jan. 2, 1997, Spencer Rich, "Battling the High Prices Medicare Pays for Drugs," *The Washington Post*, A15.) The article included the following information:

- "For two years, the General Accounting Office and the Inspector General of the Department of Health and Human Services have bombarded Congress and Medicare program officials with a simple, money-saving message: The prices Medicare pays doctors and drug suppliers for outpatient drugs are too high." (*Id.*)

- "[D]octors can buy drugs from a supplier at less than the AWP, then bill Medicare for the full AWP price. 'They buy at a substantial discount and bill Medicare for a price based on AWP'. . . ." (*Id.*)

- "In order to change the situation, HCFA proposed reimbursing doctors only for the amount they pay for the drugs." (*Id.*)

United States' Response: The United States does not dispute that in June 1997 the Washington Post published an article headlined "Battling the High Prices Medicare Pays for Drugs." Roxane has selectively quoted excerpts from the article; the entirety of the article referenced is the best evidence of its content. This article is and contains hearsay. The United States does not dispute that pharmacies can purchase drugs at discounts from AWPs. The United States disputes the

materiality of the article to Roxane's liability under the FCA. The article does not mention Roxane or refer to the Subject Drugs.

34. In June 1997, prior to the enactment of the Balanced Budget Act of 1997, the Committee on the Budget of the House of Representatives filed a report, which contained an explanation of why Congress was changing the reimbursement rate for drugs and biologicals. (H.R. Rep. No. 105-149, at 1353-54 (1997), Comm. on the Budget, Report to Accompany H.R. 2015, The Balanced Budget Act of 1997). The report included the following "Reason for Change":

- "The Inspector General for the Department of Health and Human Services has found evidence that over the past several years Medicare has paid significantly more for drugs and biologicals than physicians and pharmacists pay to acquire such pharmaceuticals. For example, the Office of Inspector General reports that Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs." (*Id.* at 1354.)

United States' Response: The United States does not dispute that in June 1997 the Committee on the Budget of the House of Representatives filed a report to accompany HR 2015 or that Roxane has quoted from that report. The specific example noted is for oncology drugs which are not at issue in this case.

35. In December 1997, the OIG published a report comparing drug acquisition prices with Medicare allowances for prescription drugs. (Tab 97, Schering Ex. 5, OIG 1997, *Excessive Medicare Payments for Prescription Drugs* (Dec. 1997 OIG Report).) Using 1995 data on twenty-two of the most commonly-used drug codes, the OIG concluded that "Medicare and its beneficiaries are making excessive payments for prescription drugs." (*Id.* at ii, 2-3.) The OIG recommended to HCFA that it "reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate." It further noted: "We do not believe that the reimbursement methodology for prescription drugs recently adopted by Congress [95 percent of AWP] will curtail the excessive drug payments we've identified in the Medicare program. In this report we've identified Medicare allowances that were 11 to 900 percent greater than drug prices available to the physician and supplier communities." (*Id.* at iii.) The OIG report further stated and concluded the following:

- "The published AWPs . . . bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs." (*Id.* at ii.)

- "HCFA's proposal in the President's 1998 budget that would have required physicians to

bill Medicare the actual acquisition cost for drugs was not adopted by Congress." (*Id.* at iii.)

- "Medicare allowed between 2 and 10 times the actual average wholesale prices offered by drug wholesalers and group purchasing organizations for 8 of the 22 drugs reviewed. For one drug, Medicare allowed 900 percent more than the average price available for the drug in 1995 and 673 percent more in 1996." (*Id.* at 8.)

- "Medicare allowances were also significantly higher than acquisition costs for the remaining 14 drugs reviewed. Medicare allowed 60 to 95 percent more than the actual average wholesale price for 3 drugs in 1995 and 2 drugs in 1996. Medicare allowed amounts were higher by 20 to 50 percent for 9 drugs in 1995 and 8 drugs in 1996. Reimbursement was between 11 and 18 percent more for the remaining 2 drugs in 1995 and 4 drugs in 1996." (*Id.*)

- The OIG included a chart depicting Medicaid reimbursements for seven drugs that each exceeded acquisition costs by over 100 percentage points. (*Id.*)

- "Based on the differences found between Medicare allowed amounts and actual wholesale prices, it is apparent that the current Medicare reimbursement methodology is based on an [sic] significantly inflated AWP statistic which bears little resemblance to actual wholesale prices available in the marketplace." (*Id.* at 9.)

United States' Response: The United States does not dispute that in December 1997, the OIG published a report entitled "Excessive Medicare Payments for Prescription Drugs." Roxane has quoted selectively from that document, and this report does not refer to Medicaid. The entirety of the report referenced is the best evidence of its content. The United States does not dispute that pharmacies could buy drugs at discounts from AWP. The United States disputes the materiality of the report to Roxane's liability under the FCA, however. First, the report does not mention Roxane or refer to any of the Subject Drugs. Second, the "spreads" referred to in the report are smaller than most of those created by Roxane for the Subject Drugs. Third, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was

aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs, starting with the title ("Excessive Medicare Payments").

36. HCFA's official response to the 1997 OIG Report acknowledged and concurred with the OIG's findings and recommendations:

- "The findings contained in the report indicate that Medicare is making excessive payments for prescription drugs. The published AWPs currently used by Medicare carriers to determine reimbursement do not resemble the actual wholesale prices which are available to the physician and supplier communities that bill for these drugs." (Tab 97, Schering Ex. 5, Dec. 1997 OIG Report at D-2.)

- "We agree with OIG's findings and recommendations. We included a provision in the President's 1998 budget bill that would have eliminated the markup for drugs billed to Medicare by requiring physicians to bill the program the actual acquisition cost for drugs. Unfortunately, this provision was not enacted, but we will pursue this policy in other appropriate ways." (*Id.* at D-3.)

United States' Response: The United States does not dispute that HCFA prepared an official response to the 1997 OIG Response. Roxane has selectively quoted from that response; the entirety of the response referenced is the best evidence of its content. The paragraph starting "We agree with the OIG's findings and recommendations" is taken out of context, in that it was stated in reference to OIG's recommendation that "HCFA should examine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate." The United States disputes the materiality of the report to Roxane's liability under the FCA. First, the response does not mention Roxane or refer to any of the Subject Drugs. Second, the "spreads" referred to in the response are smaller than most of those created by Roxane for the Subject Drugs. Third, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not

review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, language in the response itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs since HCFA concurs with the OIG's findings and recommendations.

37. Robert Vito, who worked in the OIG Office of Audit Services from 1978 through 1990, and who has worked for the Philadelphia office of the OIG Office of Evaluation and Inspections since 1990 (Tab 55, 06-19-07 Vito Dep. 31; 32-33), understood that AWP was not an actual acquisition cost and testified that by 1997, the OIG understood that on average drugs could be obtained at 42.5 percent below AWP. (Tab 56, 02-05-08 Vito Dep. 861-62.) This equates to a spread of 74 percent using Plaintiffs' methodology.

United States' Response: The United States does not dispute that Mr. Vito worked for the OIG from 1978-1990. The United States disputes Roxane's characterization of the testimony referred to in Paragraph 37. The witness qualified his statements: "Again what you read to me is exactly what it says here, but I don't know if there is anymore in this report that would change whatever the answer to that question is about qualifying or not, but what you read is exactly what is written here. And that "... I don't know if they used 200 generics or if it was all generics or what exactly their detail was." (Tab 56, at 862-863) Mr. Vito did not testify as to any government publication, policy, or statement approving Roxane's reporting of inflated AWPs for the Subject Drugs. To the extent his testimony relates to an OIG report the document referenced speaks for itself.

38. By December 1997, David Tawes, current Director of the Medicare and Medicaid Pricing Drug Unit in the Philadelphia office of the OIG Office of Evaluation and Investigations, understood that AWP was not an actual acquisition cost:

- "[T]he AWPs printed in the compendia were not reflective of actual wholesale prices." (Tab 52, 12-13-07 Tawes Dep. 875.)

- The December 1997 report "was intended to communicate to CMS and HCFA that published AWPs were not actual wholesale prices." (*Id.*)

United States' Response: The United States does not dispute the statements in this paragraph except that in 1997 Mr. Tawes had just started his employment with OIG and was merely a program analyst, not Director of the Medicare and Medicaid Pricing Drug Unit in the Philadelphia office of the OIG. (Fauci Exhibit 178 (4/24/2007 David Tawes Dep.), at 31-32) The report referenced does not mention Roxane or the Subject Drugs.

39. Tawes was also aware of Ven-A-Care's allegations by 1997. He testified that by 1997, the OIG had access to catalog pricing from Ven-A-Care, which the OIG used to compile its 1997 reports on excessive drug reimbursement under Medicare and Medicaid. (Tab 51, 4-25-07 Tawes Dep. 385-86; Tab 52, 12-13-07 Tawes Dep. 704.)

United States' Response: The United States disputes that the statements in this paragraph accurately reflect the testimony of Mr. Tawes. He testified that he had access to certain catalog prices provided by Ven-A-Care. The OIG used some of these prices in compiling its 1997 report. (Tab 51, at 386)

40. In a 1997 radio address to the nation, former President Clinton discussed AWP inflation and specifically noted spreads of up to 1000%, "one tenth of the published price." President Clinton stated:

- "[O]ur Medicare program has been systematically overpaying doctors and clinics for prescription drugs . . . Now, these overpayments occur because Medicare reimburses doctors according to the published average wholesale price – the so-called sticker price – for drugs. Few doctors however, actually pay the full sticker price. In fact, some pay just one tenth of the published price." (Tab 98, Abbott Ex. 156, 12-13-1997 Radio Address to the Nation.)

- "Sometimes the waste and abuses aren't even illegal; they're just embedded in the practices of the system.... [T]hese overpayments occur because Medicare reimburses doctors according to the published average wholesale price, the so-called sticker price, for

drugs." (*Id.*)

United States' Response: The United States disputes that in his radio address former President Clinton mentioned spreads of up to 1000%. Further the language selectively quoted by Roxane is taken out of context and misleading. The entirety of the document referenced is the best evidence of its content. The United States does not dispute that in 1997 physicians could purchase drugs at a discount from AWP. The United States disputes the materiality of the cited statements to Roxane's liability under the FCA. The former President did not indicate approval of the reporting of inflated AWPs to increase spreads; on the contrary, the President referred to "cracking down" on Medicare abuse and to "overpayments" resulting from reimbursing on AWPs. Moreover, the remarks do not mention Roxane or the Subject Drugs.

41. In January 1998, HCFA issued a Program Memorandum, which concluded that AWP is "not a true discounted price and, therefore, does not reflect the cost to the physician or supplier furnishing the drug to the Medicare beneficiary." (Tab 99, Abbott Ex. 1014, HCFA "Implementation of the New Payment Limit for Drugs and Biologicals," *Program Memorandum Intermediaries/Carriers*, Transmittal No. AB-97-25, Jan. 1998 (1998 Medicare Bulletin).)

United States' Response: The United States does not dispute that in January 1998 HCFA issued a program memorandum entitled "Implementation of the New Payment Limit for Drugs and Biologicals." Roxane has selectively quoted from that program memorandum; the entirety of the document referenced is the best evidence of its contents. The United States disputes that the memorandum "concluded" anything, since its express purpose is to "furnish. . . instructions needed to implement § 4556 of the Balanced Budget Act of 1997," and it is not a report of a study or investigation. In any event, responsible officials at Roxane never read the memorandum and admitted they did not rely upon such government documents in setting prices for their drugs. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 31:1 - 31:8; 32:17 - 37:22; 33,

158 - 162)

42. On March 19 and 20, 1998, Ven-A-Care met with representatives from the majority of state Medicaid programs, the National Association of Medicaid Fraud Control Units ("NAMFCU"), and Nancy-Ann Min DeParle of HCFA, respectively, and presented detailed information about "grossly excessive payments," involving spreads frequently in the hundreds of percents, and up to 3,000%. (Tab 1, 3-6-08 Bentley Dep. 451-54, 597; Tab 33, 12-8-08 Jones Dep. 811-12; (Tab 32, 3-19-08 Jones Dep. 558, 588; Tab 36, 3-17-08 Lockwood Dep. 578.) Ven-A-Care also described "how the spread was used as a marketing tool, how manufacturers sold their drugs to particular entities using that spread." (Tab 33, 12-8-08 Jones Dep. 810.)

United States' Response: The United States disputes the statements in this paragraph. Roxane has selectively excerpted out of context from various depositions in a manner that is misleading. Further Roxane has misquoted the testimony. Mr. Bentley stated they met with Ms. Min DeParle on March 2, 1998. The cited testimony does not indicate specifically what was presented to her. (Tab 1, at 453, 456-7) Mr Jones testified that at a NAMFCU meeting they presented an example of Abbott drugs with spreads of "thousands of per cents" not 3000 percent (Tab 33, at 811-12) The citation to Dr. Lockwood's deposition has nothing to do with the allegations of this paragraph. The deposition pages referenced in their entirety speak for themselves.

43. Indeed, throughout the 1990s, there was widespread communication between Ven-A-Care and various Governmental individuals regarding reimbursement for pharmaceuticals under the Medicare and Medicaid programs, including the following:

- On June 25, 1996, Zachary Bentley, a Ven-A-Care principal, sent a letter to Keith Lynn at the Senate Finance Committee, stating "Billion dollar & annual loss of the Medicare & Medicaid programs thru fraud & abuse while the DOJ & HHS stand by & watch the thieves 'Rob the Bank'." (Tab 100, Abbott Ex. 571, Summary Exhibit at 1 (excerpted pages due to voluminous document).) Bentley attached the *Barron's* "Hooked on Drugs" article. *Id.*

- On June 12, 1997, Zachary Bentley and T. Mark Jones wrote to HCFA Administrator Dr. Bruce Vladeck, stating that for "the past six years, VAC's officers, directors and legal counsel have made countless telephone calls, written numerous letters, created numerous reports and made detailed presentations to HCFA and other responsible governmental officials detailing the grossly excessive, price gouging reimbursements that the Medicare

Program is making . . . ." (*Id.* at 11.)

- On December 3, 1996, Bentley and Jones followed up on the letter to Dr. Vladeck with a letter to Secretary Shalala, informing her that "literally hundreds of millions of dollars" are wasted in "Medicare and Medicaid program funds." (*Id.* at 8.)

United States' Response: The United States does not dispute that there were various communications between Ven-A-Care and Government officials regarding reimbursement for certain pharmaceuticals in the 1990s, or that the letters referenced were sent on or about the dates stated on them. Roxane has selectively excerpted, out of context and in a manner that is misleading, from the documents referenced in this paragraph. The quote from the June 12, 1997, letter to Dr. Bruce Vladeck referred to "the grossly excessive price gouging reimbursements that the Medicare program is making for TPN [Total Parental Nutrition]," which pharmaceutical is not at issue in this case. The December 3, 1996, letter to Donna Shalala refers to the letter referencing TPN. Each of these letters and documents being referenced is the best evidence of its content. Answering further, the United States does not dispute that providers can purchase pharmaceuticals at a discount off of AWP.

44. During this time, Ven-A-Care had also been making presentations to most of the states' governments. (Tab 33, 12-8-08 Jones Dep. 810.) Ven-A-Care's presentations included an allegation that state Medicaid programs have made "excessive reimbursements to providers from 30% to 3000% over the providers' true cost." (Tab 101 at 1, Abbott Ex. 559, Ven-A-Care Texas Presentation.)

United States' Response: The United States disputes the statements of this paragraph. Mr. Jones testified that in March 1998 Ven-A-Care made a presentation to NAMFCU which was attended by representatives of almost all States (Tab 33, at 809-810) Ven-A-Care also made presentations to certain states in 1998. The United States does not dispute that presentations contained the information in the second sentence of this paragraph.

45. In 1998, the OIG published a report entitled, "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs." (Tab 102, Lockwood Ery 19, OIG 1998, *Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs* (1998 OIG Report).) In its report, the OIG stated and concluded the following:

- "Because AWP is usually used as a basis for reimbursement at the pharmacy level, manufacturers can use it as a marketing tool to gain market share. For example, by increasing AWP, manufacturers can give pharmacies more Medicaid reimbursement without having to make additional rebate payments. The drug industry currently treats AWP as a published list price rather than a true wholesale price." (*Id.* at 5.)

United States' Response: The United States does not dispute that in 1998 the OIG published a report entitled "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs." Roxane has correctly, and selectively, quoted an excerpt from that report; the entirety of the referenced report is the best evidence of its contents. The United States does not dispute that in 1998 pharmacies could buy drugs at discounts from AWP. The United States disputes the materiality of the report to Roxane's liability under the FCA, however. The report does not mention Roxane or refer to any of the Subject Drugs; indeed, the report studied "brand name drugs" only. Moreover, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18)

46. In 1999, the Department of Health and Human Services ("HHS") wrote a report to Congress entitled "The Average Wholesale Price for Drugs Covered under Medicare." (Tab 103 at 8, Abbott Ex. 200, *1999 HHS Report to Congress: The Average Wholesale Price for Drugs Covered under Medicare* (1999 HHS Report).) The report stated and concluded the following:

- AWP "as an unregulated, suggested price, typically set by the manufacturer . . . bears no consistent or predictable relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace." (*Id.* at 8.)

- "For the past 13 years, the Office of Inspector General . . . has issued a series of reports that consistently show a finding that the Medicare program overpays for the drugs and biologicals it covers. This is because most drugs can be obtained at a much lower cost than AWP. To address this problem, the President's 1997 budget contained a legislative proposal that would have based payment on the lower of the billed charge or the actual acquisition cost (AAC) for the drug of the physician or supplier billing Medicare. However, as discussed above, in the BBA, Congress rejected this proposal in favor of the current rule, which is to pay based on the lower of the billed charge, or 95 percent of AWP." (*Id.* at 2.)

- There is an average markup for AWP of 41% from the drugs' wholesale catalog price advertised to physicians and suppliers. (*Id.*)

- "AWP is not a well-defined concept nor is it regulated in any way." (*Id.*)

United States' Response: The United States does not dispute that in 1999 HHS wrote a report to Congress entitled "The Average Wholesale Price for Drugs Covered under Medicare." Roxane has selectively quoted from that report; the entirety of the referenced report is the best evidence of its contents. The United States disputes the materiality of the report to Roxane's liability under the FCA. First, the report does not mention Roxane or refer to any of the Subject Drugs. Second, the "spreads" referred to in the report are smaller than most of those created by Roxane for the Subject Drugs. Third, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs; such AWPs were considered to be

"inflated," resulting in excessive "overpayments." (*See*, *e.g.,* Tab 104, at 1 (referring to overpayments and the "problem" of using AWP as a basis of reimbursement))

47. On September 1, 1999, Representative Pete Stark of California issued a press release that stated "AWP is a "phony . . . system," a "joke on the taxpayer," and an acronym for "Ain't What's Paid." (Tab 130, 9-1-1999 Stark Press Release, "Drug Utilization Soars as Profits Soar.")

- In 1999, HCFA commissioned a study and report by Myers & Stauffer regarding high-cost drugs under the proposed Outpatient Prospective Payment System. (Tab 105, September 8, 1999, "High Cost Drugs Under the Outpatient Prospective Payment System," Kathal Technologies at 4.) The study reported discounts off of AWP for generic drugs that averaged 58% (a spread of 138%) and climbed as high as 90% (a 900% spread). (*Id.*)

United States' Response: The United States disputes this statement. Congressmen Stark's press release of Sept 1, 1999, at Tab 130, contains no such statement. Rather it notes that "use of this old product only started soaring when the profit spread exploded." The bullet beneath Paragraph 47 has no relation to Tab 130. The report it references is only a draft. The United States disputes the materiality of the report to Roxane's liability under the FCA. The "spreads" referred to in the report are smaller than many of those created by Roxane for the Subject Drugs. Moreover, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18)

48. Despite the OIG's finding in 1997 that actual acquisition costs for generic drugs were on average 42.5 percent lower than AWP (Tab 89, Roxane Ex. WY 4 at 4, Aug. 1997 OIG Report) as of 1999, the average state discount was 10.4 percent off of AWP. (Tab 106 at 3, Abbott Ex. 121, July 2001 OIG Report, *Cost Containment of Medicaid HIV/AIDS Drug Expenditures* (citing National Pharmaceutical Council, "Pharmaceutical Benefits Under State Medical Assistance Programs," 199, p. 4-57).)

United States' Response: The United States does not dispute that in July 2001 OIG issued a report *"Cost Containment of Medicaid HIV/AIDs Drug Expenditures.*" Roxane has selectively quoted from that report; the entirety of the report referenced is the best evidence of its content. The United States disputes the materiality of the report to Roxane's liability under the FCA. First, the report deals with HIV/AIDS retroviral drugs, not the Subject Drugs. In any event, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18)

49. In 1999-2000, the House Committee on Commerce conducted a Congressional investigation into reimbursement based on AWP. Hearings were held on the issue, and the OIG sent manufacturers investigation letters. (Tab 107, Abbott Ex. 212, 5-5-00 Rep. Bliley letter to Shalala at 1; Tab 109, Julie Appleby, "House Committee Asks Drug Firms to Justify Pricing Policy," *USA Today*, May 10, 2000, at 1B.)

United States' Response: The United States does not dispute this paragraph, except the hearings occurred in 2000 as noted in the referenced documents.

IV. GOVERNMENT POLICY DECISIONS TO MAINTAIN AWP AND NOT USE ACTUAL ACQUISITION COST AS THE BASIS FOR REIMBURSEMENT: 1992 – 1999

50. The 1991 Medicare regulations provided that reimbursement could be based on AWP or EAC. Any EAC was to be based on carrier surveys of actual provider invoice prices. (56 Fed. Reg. 59502, 59525) HCFA did not pursue surveys of providers' acquisition costs. (Tab 59, 5-4-07 Vladeck Dep. 179-82; Tab 60, 6-21-07 Vladeck Dep. 384.) Although in March 1994, HCFA initially instructed carriers to survey providers' actual acquisition costs, in August 1994, HCFA retracted its instruction and mandated that the carriers "immediately suspend any data collection efforts," because the Office of Management and Budget ("OMB") had not approved the survey. (Tab 108, Abbott Ex. 304, Mar. 22, 1994, Mirabal Letter to All Region II HCFA Medicare Carriers; Tab 110, Abbott Ex. 309, July 25, 1996 Debus Letter to Steffen.) Ultimately, HCFA never undertook the surveys of providers' acquisition costs. (Tab 60, 6-21-07 Vladeck Dep. 384,

386.) As a result, AWP became the default reimbursement methodology for all Medicare claims until January 1, 1998.

United States' Response: The United States does not dispute the statements in this paragraph except to state that AWP was not "the default reimbursement methodology" but a permissible reimbursement methodology under the regulations, 56 Fed. Reg. 59,502.

51. In February 1996, Representative Pete Stark proposed legislation that would have changed Medicare's payment rate from 100 percent of AWP to 83 percent of AWP. (Tab 92, Roxane Ex. 30, Feb. 27, 1996 Rep. Stark Statement to House of Reps.) Congressman Stark's legislation was never adopted.

United States' Response: The United States disputes the statements in the first sentence of this paragraph, as Representative Stark's proposal was to use AWP minus 30 as an arbitrary reimbursement number, and applied only to oral anti-cancer drugs. Those drugs are not at issue in this case. The entirety of the proposed legislation is the best evidence of its content. The United States does not dispute the second sentence of this paragraph. The United States notes that Congressman Stark's statement at Tab 92 indicates disapproval of inflated AWPs and indicates his view that Medicare is "being defrauded." Moreover, the United States disputes Roxane's characterization of legislative history. Further, the content of a proposed bill and the action or inaction of Congress are matters documented in the formal legislative record, which Roxane has not presented. The testimony of a fact witness concerning the content of such legislative action or inaction is not relevant or admissible. *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004).

52. In 1997 and 1998, as part of the Balanced Budget Acts, the Clinton Administration proposed abandoning an AWP-based reimbursement method altogether and shifting to a system based on actual acquisition costs. Congress rejected the proposals for both years. (Tab 93, Abbott Ex. 213, 5-31-00 Shalala letter to Rep. Bliley; Tab 59, 5-4-07 Vladeck Dep. 178-79; Tab 111, August 2001 Memo from CRS to the House Committee on Energy and Commerce, "Regulatory

and Legislative History of Medicare Drug Reimbursement Based on Average Wholesale Price" at CRS 6 ("CRS Memo, August 2001").) Congress instead adopted a 5% discount off of AWP such that Medicare Part B drugs were reimbursed at "the lower of 95 percent of the median generic AWP or 95 percent of the lowest brand AWP." (Tab 112, Abbott Ex. 209, 63 Fed. Reg. 58813, 58850 (Nov. 1998)).

United States' Response: The United States disputes the statements in this paragraph as they do not accurately reflect the contents of the documents to which reference is made. For example, the Shalala letter refers to the "estimated acquisition cost approach." The United States does not dispute that Congress adopted a 5% discount off of the AWP and that CMS promulgated a rule changing the reimbursement of multi-source drugs under Medicare Part B to be 95% of the "lesser of the median average wholesale price for all sources of the generic forms of the drug or biological." 42 C. F.R. Sec. 405.517(b) and (c); 63 Fed. Reg 58,813. The United States disputes Roxane's characterization of legislative history. Further, the content of a proposed bill and the action or inaction of Congress are matters documented in the formal legislative record, which Roxane has not presented. The testimony of a fact witness concerning the content of such legislative action or inaction is not relevant or admissible. *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004). The United States disputes the materiality of the cited documents since there is no evidence that responsible Roxane officials ever read these documents, and they testified they did not rely on such documents in setting prices for their drugs. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 30-32, 141, 158-162)

53. In 1998, Congress also granted CMS "inherent reasonableness" authority, allowing it to provide guidelines to determine "an amount that is realistic and equitable" when application of Medicare Part B reimbursement rules "results in the determination of an amount that [. . .] is not inherently reasonable." (Tab 111 at CRS-5, CRS Memo, August 2001.) This authority allowed CMS to reduce payment rates by up to 15 percent. (Tab 113, Abbott Ex. 130, BBA § 4316, PL 105-33, 42 U.S.C. § 1395u(b)(8)(B).)

United States' Response: The United States does not dispute that in August 2001, in response to "a request for a regulatory and legislative history of Medicare drug reimbursement based on the average wholesale price (AWP) of the drug," the Congressional Research Service issued the Memorandum at Tab 111. Roxane has selectively quoted from the Memorandum; the entirety of the document referenced is the best evidence of its contents. The United States disputes the materiality of the Memorandum to Roxane's liability under the FCA, since Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) The United States does not dispute the contents of PL 105-33 (Tab 113).

54. Pursuant to its inherent reasonableness authority, in late 1998, HCFA attempted to reduce albuterol payments by 11 percent. (Tab 111 at CRS-5, CRS Memo, August 2001; Tab 114, Abbott Ex. 94, OIG January 2001, *Medicare Reimbursement for Prescription Drugs*, at 2, Appendix F, p. 2 (Jan. 2001 OIG Report).) In 1999, Congress rejected this reduction and suspended HCFA's ability to exercise the inherent reasonableness authority until further investigation was done by the GAO and until the Secretary of the Department of Health and Human Services published final regulations responding to comments received in response to the January interim final regulations. (Tab 111 at CRS-5, CRS Memo, August 2001; Tab 114, Abbott Ex. 94, Jan. 2001 OIG Report, at 2, Appendix F, p. 2; [BBA 1999, § 223, Pub. L. No. 106-113, 113 Stat. 1501A-352-53 (1999); H. Rep. No. 479, 106th Cong. 1st Sess. 876-877 (1999)].)

United States' Response: The United States disputes that Roxane has accurately paraphrased from the document referenced in this paragraph. The January 2001 OIG report *"Medicare Reimbursement for Prescription Drugs"* states at p. 2: " However, before any lower prices could be implemented Congress suspended the use of inherent reasonableness through provisions of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999." The documents

referenced in their entirety speak for themselves. The United States disputes Roxane's characterization of legislative history. Further, the content of a proposed bill and the action or inaction of Congress are matters documented in the formal legislative record, which Roxane has not presented. The testimony of a fact witness concerning the content of such legislative action or inaction is not relevant or admissible. *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004). The United States disputes the materiality of the cited documents and reports to Roxane's liability under the FCA. First, the reports do not mention Roxane or refer to any of the Subject Drugs. Moreover, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) In addition, the reports do not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPs. Indeed, language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs; such AWPs were considered to be "inflated," resulting in excessive or "overpayments." (*See, e.g.,* Tab 114, at iii ("current AWP-based reimbursement method. . . cheats taxpayers"))

55. In 1999 and 2000, HCFA submitted a proposal by the President to change Medicare reimbursement to 83 percent of AWP. (Tab 93, Abbott Ex. 213, 5-31-00 Shalala Letter to Rep. Bliley.) Congress rejected the proposal. (Tab 111 at CRS-6, CRS Memo, August 2001.)

United States' Response: The United States does not dispute the statements in this paragraph. The United States disputes the materiality of the information to Roxane's liability under the FCA, however, since Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications

that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Further, the United States disputes Roxane's characterization of legislative history. Further, the content of a proposed bill and the action or inaction of Congress are matters documented in the formal legislative record, which Roxane has not presented. The testimony of a fact witness concerning the content of such legislative action or inaction is not relevant or admissible. *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004).

56. Dr. Vladeck, HCFA Administrator from 1993 to 1997 (Tab 59, 5-4-07 Vladeck Dep. 77-78), explained that the reason HCFA did not change the reimbursement system was because of political reasons:

- "I think it is fair to say as well that I believed, as – as far back as '95, that 85 percent of average wholesale price as a payment method was inferior to something closer than average acquisition cost, but that the administrative difficulties, and the potential administrative burden on physicians as a political issue, if not a real issue, made it likelier that we would be able to succeed with the legislative proposal still tied to AWP than one that went all the way back to its acquisition costs." (*Id.* 178-179.)

- Urologists, other oncologists, and the American Society of Clinical Oncology strongly opposed proposals to pay less than 100% of AWP and to move away from AWP as a reimbursement basis. (*Id*. 194; Tab 60, 6-21-07 Vladeck Dep. 326, 333-34, 366.)

- "There are political considerations that, in addition to legal considerations, prevented us from seeking to change the policy administratively. And then there was political opposition to – efforts to change the law itself." (Tab 60, 6-21-07 Vladeck Dep. 379-82.)

United States' Response: The United States disputes the conclusion of the first sentence of this paragraph, as Dr. Vladeck was explaining why there was a lack of agreement on how to make a change. Further, he testified that HCFA "proposed, a number of times, to change the methodology." (Tab 59, at 178) Roxane has selectively quoted from the testimony of Dr. Vladeck. The United States disputes Roxane's characterization of legislative history. Further,

the content of a proposed bill and the action or inaction of Congress are matters documented in the formal legislative record, which Roxane has not presented. The testimony of a fact witness concerning the content of such legislative action or inaction is not relevant or admissible. *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004). In any event, the testimony cited does not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPs, and there is no evidence of any formal policy statement demonstrating that a federal official approved of Roxane's reporting of its AWPs. Further the evidence shows that Roxane never communicated to the United States its practice of reporting AWPs that are not an actual average wholesale price of Roxane drugs. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 140:22, 141:1 -141:4, 207:9 - 207:8, 208:8 - 208:18, 218:1 - 218:10)

57. Thomas Scully, senior White House staff member on health care from 1990-91, and HCFA/CMS Administrator from May 2001 through January 2004, testified that Medicare reimbursement was also affected by politics: "politics is politics and that's what drove this issue for 10 years." (Tab 46, 5-15-07 Scully Dep. 173.)

United States' Response: Roxane has correctly, but selectively quoted from the deposition of Mr. Scully. The testimony does not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPs, and there is no evidence of any formal policy statement demonstrating that a federal official approved of Roxane's reporting of its AWPs. Further, the evidence shows that Roxane never communicated to the United States Roxane's practice of reporting inflated AWPs that are not an actual average wholesale price of Roxane drugs. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 140:22, 141:1 - 141:4, 206:1 - 206:6, 207:9 - 207:18, 218:1 - 218:10) Further, the United States disputes Roxane's characterization of legislative history. Further, the content of a proposed bill and the

action or inaction of Congress are matters documented in the formal legislative record, which Roxane has not presented. The testimony of a fact witness concerning the content of such legislative action or inaction is not relevant or admissible. *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004).

V. INFORMATION AVAILABLE TO THE GOVERNMENT REGARDING THE DIFFERENCE BETWEEN AWP AND ACTUAL ACQUISITION COSTS: 2000 - 2001

58. A May 2000 *New York Times* article discussing the use of pharmacy benefit management companies to control drug costs quoted a pharmaceutical consultant, who said that AWPs "are not an average, not wholesale, and not a price, other than what employers pay." (Tab 115, May 7, 2000 Milt Freudenheim, "New Questions on Drug Plans as Costs Soar," *New York Times* at 3.)

United States' Response: The United States does not dispute that the quoted statements appeared in a *New York Times* article in May 2000. The article is and contains hearsay. The United States does not dispute that in 2000 pharmacies could purchase drugs at a discount from AWP. The United States disputes the materiality of the article to Roxane's liability under the FCA, however. The article does not mention Roxane or refer to any of the Subject Drugs. The article does not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPS.

59. In May 2000, House Commerce Committee Chair Thomas Bliley wrote letters to HHS Secretary Donna Shalala and Administrator Min DeParle requesting that HCFA identify all actions taken by the Administration to investigate and assess the accuracy of AWP. (Tab 107, Abbott Ex. 212, May 2000 Rep. Bliley Letter to Shalala; Tab 116, Abbott Ex. 218, September 2000 Letter to Min DeParle.)

United States' Response: The United States does not dispute that in May 2000 Congressman Bliley wrote letters to HHS Secretary Donna Shalala and Administrator Min DeParle. Roxane has selectively quoted and paraphrased from these letters; the entirety of the letters referenced are

the best evidence of their contents. The United States disputes the materiality of the letters to Roxane's liability under the FCA, however. First, the letters do not mention Roxane or refer to any of the Subject Drugs. Moreover, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/8/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, language in the letters itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs; such AWPs were considered to be "inflated," resulting in excessive or "overpayments." (*See, e.g*, Tab 93, at 1 (referring to "excessive" reimbursements and explaining that DOJ and State MFCU's were obtaining "more accurate data" than that reported)).

60. On May 31, 2000, Secretary Shalala responded to Rep. Bliley, stating the following:

- By 1998, the OIG knew that payments based on AWP were "11 to 900 percent greater than prices available to the physician community." (Tab 93, Abbott Ex. 213, (5-31-00 Letter. from Shalala to Rep. Bliley, at 2).)
- In 1997 and again in 1998, "President [Clinton] proposed legislation to pay physicians their actual acquisition costs . . . . Unfortunately, Congress did not adopt the Administration's proposal." (*Id.* at 1-2.)
- In 1999 and 2000, the Clinton Administration proposed further discounts off of AWP that Congress rejected. (*Id.* at 2.)
- HCFA planned to utilize data being gathered by the DOJ to make administrative changes to the AWP reimbursement system. (*Id.* at 2.)

United States' Response: The United States does not dispute that on May 31, 2000, Secretary Shalala responded to Representative Bliley. Roxane has selectively quoted and paraphrased from her response; the entirety of the letter referenced is the best evidence of its content. The United

States disputes the materiality of the letter to Roxane's liability under the FCA. First, the letter does not mention Roxane or refer to any of the Subject Drugs. Second, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, the letter does not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPs.

61. In August 2000, the *New York Times* reported that while the Clinton administration was planning to decrease Medicare reimbursements, "[a]t least 120 members of Congress . . . have signed letters to Dr. Shalala expressing alarm about the administration's plans." Chris Jennings, health policy coordinator at the White House, noted that "[t]he current reimbursement policy is unsustainable. It's appropriate to reimburse doctors for the cost of the drugs they purchase, but they should not be allowed to mark up the price by 20, 70 or 700 percent, as they do now in some cases." (Tab 117, August 6, 2000 Robert Pear, "Administration Plans Cuts in Some Drug Payments," *New York Times*, p. 2.)

United States' Response: The United States does not dispute that on August 6, 2000, the *New York Times* published an article headlined "Administration Plans Cuts in Some Drug Payments." The United States disputes that Roxane has accurately quoted from the article, which specifically refers to "an effort to.... cut payments for anti-cancer drugs administered to patients in doctors offices." These drugs are not at issue in this case. Roxane has selectively quoted and paraphrased from this article; the article in its entirety is the best evidence of its contents. Further, the article is and contains hearsay. The United States disputes the materiality of the article to Roxane's liability under the FCA, in any event. The article does not mention Roxane

or refer to any of the Subject Drugs. The article does not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPs.

62. In September 2000, Representative Bliley responded to Administrator Min DeParle's May 2000 letter. He criticized the use of the new AWPs that were closer to acquisition cost, citing his concern that it would "impact quality and access to care issues." (Tab 116, Abbott 218, 9-25-00 Letter from Rep. Bliley to Min DeParle.) Rep. Bliley added the following:

- "Echoing the previous findings of numerous reports by the Department of Health and Human Services Office of Inspector General (OIG), the Committee has uncovered substantial evidence that Medicare reimburses health care providers at prices dramatically more than what they actually pay for certain drugs." (*Id.* at 3.)

United States' Response: The United States does not dispute that in September 2000, Representative Bliley responded to Administrator Min DeParle's letter. The United States disputes that in the second sentence of this paragraph Roxane has accurately paraphrased that response. Representative Bliley stated the announcement had been made without "consideration of how these price changes would impact quality and access to care issues." Roxane has selectively quoted a paragraph from that response; the entirety of the response referenced is the best evidence of its content. Moreover, the letter does not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPs.

63. In September 2000, Rep. Stark again issued a press release, alleging "massive abuse of public . . . insurance plans by a number of the nation's major pharmaceutical companies." (Tab 119, 9-27-00 Stark Press Release at 2.)

United States' Response: The United States does not dispute that in September 2000, Representative Stark issued a press release. Roxane has selectively quoted from a letter referred to in that press release; the entirety of the press release referenced is the best evidence of its content. The United States does not dispute that providers can obtain drugs at a discount from AWP. The United States disputes the materiality of the press release to Roxane's liability under

the FCA, however. First, the press release does not mention Roxane or refer to any of the Subject Drugs. Second, the "spreads" referred to in the press release are smaller than most of those created by Roxane for the Subject Drugs. Third, responsible officials in Roxane's marketing department never read this press release, and admitted that they did not rely on such press release in setting prices for Roxane drugs. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.) at 141:10 - 141:22). Finally, language in the press release itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs; such AWPs were considered to be "inflated," resulting in excessive or "overpayments." (*See, e.g*, Tab 119 at 2 (referring to manufacturers' "plot" to inflate the cost of drugs and to the "most flagrant" consumer abuse)).

64. In January 2001, the OIG again recommended that HCFA "reduce excessive Medicare drug reimbursement amounts." (Tab 114, Abbott Ex. 94 at ii, Jan. 2001 OIG Report.) The OIG further stated and concluded the following:

- "Despite numerous attempts by HCFA to lower Medicare drug reimbursement, the findings of this report illustrate once again that Medicare simply pays too much for prescription drugs. The published AWPs that Medicare carriers currently use to establish reimbursement amounts bear little or no resemblance to actual wholesale prices that are available to physicians, suppliers, and other large government purchasers." (*Id.*)

- "The VA paid between 8 and 91 percent less than Medicare for the 24 drugs reviewed." (*Id.* at i-ii.)

United States' Response: The United States does not dispute that in January 2001 the OIG issued the report at Tab 114. Roxane has correctly, but selectively, quoted from that report; the entirety of the report referenced is the best evidence of its contents. The United States does not dispute that providers can obtain drugs at a discount from AWP. The United States disputes the materiality of the report to Roxane's liability under the FCA, however. First, the report does not

mention Roxane or refer to any of the Subject Drugs. Moreover, Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Finally, language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs; such AWPs were considered to be "inflated," resulting in excessive or "overpayments." *See*, *e.g.*, Tab 114, at ii (referring to "excessive" reimbursement amounts) and iii (reporting agency comments that current AWP-based reimbursement method "cheats taxpayers")).

65. In September 2001, at a Joint Hearing of the House Subcommittees on Health and Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, "Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers," the following statements were made and testimony was given:

- "[T]he pricing abuses have reached the point at which drug manufacturers use the 'spread' between the AWP and the actual price paid as a marketing took to sell their products. Not only does the taxpayer get gouged; so does the Medicare." (Sept. 2001 Joint Hrg. "Medicare Drug Reimbursements: A Broken system for Patents and "Taxpayers" (107th Cong., 1st Sess., Serial No. 107-65) at 7, Statement of Rep. Peter Deutsch (Sept. 2001 Joint Hrg.).)

- AWPs "aren't the average of anything, they certainly aren't wholesale, and, in fact, they aren't even prices. They are a marketing tool." (*Id.* at 11, Statement of Rep. James Greenwood.)

- "The issue on the table today critically analyzing the marketing practices of drug companies will show the immense amount of fraud perpetrated on the taxpayers and the senior citizens of this country." (*Id.* at 17, Statement of Rep. Frank Pallone.)

- "Unfortunately a lot of manufacturers' representatives are going out and marketing their respective drugs not based on the efficacy of the drug but what in fact will put the most money in either the physician's pocket or the pharmacy's pocket . . . [T]here's marketing actually going on to encourage the utilization of one drug over a competing drug by using

government funds that fund the kickback as a marketing mechanism." (*Id.* at 78, Testimony of Zachary Bentley, President of Ven-A-Care, Inc.)

United States' Response: The United States does not dispute that in September 2000 there was a joint hearing of the House Subcommittees on Health and Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, "Medicare Drug Reimbursement: A Broken System for Patients and Taxpayers." Roxane has selectively quoted and paraphrased from statements made and testimony given at that hearing; the entirety of the document referenced is the best evidence of its contents. There is no evidence that any Roxane officials read this testimony and they testified that they did not rely on any government reports in setting prices for Roxane drugs. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 208:8 - 208:18)

VI. GOVERNMENT POLICY DECISIONS: 2000 – 2001

66. In May 2000, the DOJ proposed reductions in Medicare payments by sending to HCFA and First DataBank revised AWPs for 32 Medicare drugs that were significantly lower than published AWPs. (Tab 118, Roxane Ex. 113 at 1, Sept. 8, 2000 HCFA Program Memorandum Intermediaries/Carriers, "An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program," HCFA-Pub. 60AB (9-8-00 HCFA Program Memorandum) (Tab 111 at CRS-6, CRS Memo, August 2001.)

United States' Response: The United States disputes that Roxane has accurately paraphrased the CRS memo of August 2001. The documents referenced are the best evidence of their contents. The United States does not dispute that providers can purchase drugs at a discount from AWP. The United States disputes the materiality of the referenced documents to Roxane's liability under the FCA, however. There is no evidence that officials at Roxane read these documents and they testified they did not rely on such government publications in setting prices

for Roxane drugs. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.) at 208:8 -208:18)

67. In July 2000, Congress resoundingly rejected HCFA's proposal, criticized the Administration's attempt to "redefin[e]" AWP by using amounts reflective of actual average acquisition costs, and reiterated that it intended to maintain a definition of AWP as "amounts reflected in specified publications," i.e., the list price published in compendia such as First DataBank. (Tab 120, Abbott Ex. 220 at 1-2, 7-28-00 Letter from 91 members of Congress to Shalala.) A letter signed by over 90 Congressmen specifically stated that the 1997 BBA authorized HCFA to pay based on AWPs, which were commonly known as the list prices in RedBook and other compendia, rather than the DOJ's revised AWPs that reflected acquisition costs:

- "It is important to recall that reimbursement for cancer drugs is an issue that has been repeatedly addressed by Congress over the past few years in order to respond to various Administration efforts to reduce reimbursement. Thus, Congress in 1997 instructed the Department to base reimbursement for drugs on 95% of AWP, a term widely understood and indeed defined by Department manuals to reference amounts reflected in specified publications. Later, Congress pegged reimbursement for drugs in the hospital outpatient setting to the same definition of AWP." (*Id.* at 1.)

- "It is disturbing that the Department would now seek to circumvent those congressional actions by redefining AWP. We see no basis for such action in any of our previous legislation, and certainly the Department's unilateral declaration of a new definition of AWP, with no regulatory process, is inappropriate." (*Id.* at 1-2.)

United States' Response: The United States disputes the statements in the first sentence of this paragraph. The letter was sent by a minority of the members of the House of Representatives and does not use the words "list price." Roxane has paraphrased and selectively quoted from the letter of 7/28/00. The letter states:

> Reduction in payment for chemotherapy drugs should be suspended until there has been a thorough study of the cost of administering chemotherapy in physician offices and Congress has had an opportunity to act upon that information.

Cancer drugs are not at issue in this case. Moreover, the letter does not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPs.

68. Thus, by 2000, Congress had explicit knowledge of inflated AWPs, yet advocated against utilizing the more accurate data compiled by the DOJ.

United States' Response: The United States disputes the statements in this paragraph. If by "thus" Roxane meant to refer to the letter at Tab 120, that letter stated:

> Reduction in payment for chemotherapy drugs should be suspended until there has been a thorough study of the cost of administering chemotherapy in physician offices and Congress has had an opportunity to act upon that information.

Cancer drugs are not at issue in this case. Moreover, the letter does not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPs.

69. Despite Congress's voiced opposition, in September 2000, HCFA authorized its carriers to revise downward their AWPS based on the DOJ AWPs and asked program participants to consider them, but did not require either Medicare or Medicaid programs to use the revised AWPs. (Tab 118, Roxane Ex. 113, at 1, 9-8-00 HCFA Program Memorandum.) Medicare carriers did not use the revised AWPs. (Tab 121, Abbott Ex. 221, at 1, 11-17-00 HCFA Program Memorandum.) Many states did not use the revised AWPs. (Tab 122, Abbott Ex. 95, OIG Sept. 2001, *Medicaid's Use of Revised Average Wholesale Prices*.) The Program Memorandum discussed the following:

- The Clinton Administration proposed to reimburse Medicare drugs based on "actual average wholesale prices" that the DOJ and National Association of Medicaid Fraud Control Units ("NAMFCU") had compiled, to counteract mega-spreads. (Tab 118, Roxane Ex. 113, at 1.)

- The DOJ AWPs were "more accurate wholesale prices for these drugs [and that] because purchasers often receive further discounts below the advertised wholesale catalog price . . . actual acquisition costs may be lower." (*Id.* at 1.)

United States' Response: The United States disputes that the statements in this paragraph accurately reflect the documents referenced and incorporates its response to paragraphs 67 and 68 as if fully set forth herein. Roxane has paraphrased and selectively quoted from the 9-8-00 HCFA Program Memorandum and OIG September 2001 *Medicaid's Use of Revised Average Wholesale Prices*. By way of further answer, the latter report states at p. i that 30 states did incorporate "the revised prices into their drug reimbursement methodology in some manner." The entirety of the documents referenced is the best evidence of their contents. The United

States does not dispute that providers could purchase drugs at a discount from AWP. The United disputes the materiality of the documents cited to Roxane's liability under the FCA. There is no evidence that Roxane officials read them and they testified they did not rely on such documents in setting prices for their drugs. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 141:10 - 141:22; 142:1 - 142:6; at 208:8 - 208:18) Moreover, the documents do not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPs.

70. At the same time, HCFA Administrator Nancy Min DeParle submitted a letter to Congress explaining her decision. (Tab 123, Abbott Ex. 215, 9-8-00 Ltr. from Min DeParle to Members of Congress.) Her letter stated and concluded the following:

- "[T]he Balanced Budget Act reduced Medicare payments for covered drugs from 100 percent to 95 percent of the average wholesale price. This policy captures only a small fraction of the excessive Medicare payment amounts, as average wholesale price data do not reflect actual costs for many Medicare-covered drugs. Therefore, the Administration has proposed to pay 83 percent of the average wholesale price." (*Id.* at 2.)

- "As we suggested in May, the right approach to addressing Medicare profits on drugs identified by DOJ is to pay correctly for the drugs, and at the same time make changes, as necessary, to assure that Medicare adequately pays for services related to the provision of the drugs." (*Id.*)

United States' Response: The United States does not dispute that Administrator Min DeParle sent a letter to Congress in September of 2000. Roxane has selectively quoted from that letter; the entirety of the documents referenced is the best evidence of its contents. The United States does not dispute that providers could purchase drugs at a discount from AWP. The United States disputes the materiality of the cited documents to Roxane's liability under the FCA. There is no evidence that Roxane officials read the letter, and Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price

reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Moreover, the letter does not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPs.

71. Within a few months after the DOJ AWPs were provided to Medicaid programs and to Medicare, Congress forbade even the consideration of these revised AWPs. By November 2000, they were withdrawn. In a Program Memorandum dated November 17, 2000, HCFA informed Medicare carriers that they should not use the DOJ AWPs (Tab 121, Abbott Ex. 221, 11-17-00 HCFA Program Memorandum):

- "This is to notify you that you should NOT use the Department of Justice (DOJ) data attached to PM AB-00-86 in your next update of Medicare payment allowances for drugs and biologicals. Instead, until further notice, you should delay use of this new source of average wholesale price (AWP) and use the AWP data from your usual source." (*Id.*)

- "While we continue to believe that the AWPs reported in the usual commercially available sources are inaccurate and inflated above the true wholesale prices charged in the marketplace, congressional action may preclude the use of this alternative source. To avoid the disruption that would result from a decrease in payment allowances followed by an immediate increase due to final congressional action, we are deferring use of the DOJ AWP data until further notice." (*Id.*)

United States' Response: The United States disputes the first sentence in this paragraph and states that Roxane has not provided any evidence that supports this sentence. The second sentence is also disputed as Medicaid programs could and did still use the DOJ AWPs. The HCFA Program memo applied only to Medicare carriers. The United States does not dispute that in a Program Memorandum dated November 17, 2000, HCFA informed Medicare carriers that they should not use the DOJ AWPs in their next update of Medicare payment allowances for drugs and biologicals, but delay their use. Roxane has selectively quoted from this memorandum; the entirety of the document referenced is the best evidence of its content.

72. At Congress's direction, HCFA's efforts to decrease reimbursement were once again frustrated. In its comments to the Jan. 2001 OIG Report, HCFA noted "[a]s you know, when we

have taken administrative action to reduce payments in the past, we have been blocked by Congress." (Tab 114, Abbott Ex. 94, Jan. 2001 OIG Report, Appendix F, p. 2.)

United States' Response: The United States disputes the first sentence. On December 21, 2000 Congress passed legislation that required a GAO study before HCFA could use the DOJ AWPs. Roxane has selectively quoted from HCFA's comments on the January 2001 report; the entirety of the document referenced is the best evidence of its content. The United States disputes the materiality of the statements in this paragraph to Roxane's liability under the FCA. Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Moreover, the cited document does not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPs.

73. On December 21, 2000, Congress passed legislation that prohibited HCFA from using the DOJ AWPs until GAO completed a comprehensive drug pricing study. (*Id.* at 3.)

United States' Response: The United States disputes the statement in this paragraph. On December 21, 2000 Congress passed legislation that required a GAO study before HCFA could use the DOJ AWPs for Medicare. (Tab 114, OIG (Jan. 2001) "Medicare Reimbursement of Prescription Drugs") The entirety of the document referenced is the best evidence of its contents.

VII. FEDERAL GOVERNMENT CONTINUES TO USE AND APPROVE AWP AS A BASIS FOR REIMBURSEMENT

74. The Federal Government continued to use AWP as a basis for reimbursement under Medicare until 2003 when Congress enacted the Medicare Modernization Act (MMA) and changed Medicare reimbursement from AWP-based payments to 106% of the manufacturer's

average sales price (ASP). (Medicare Modernization Act of 2003, Pub. L. 108-173,117 Stat. 2066, 2239.)

United States' Response: The United States does not dispute the statement in this paragraph.

75. Even though the Federal Government changed the Medicare reimbursement system, it continues to this day to allow most state Medicaid programs to use EAC formulas of AWP minus only a small percentage. (Tab 124, Abbott Ex. 326, 1990 Medicaid Drug Reimbursement Report.)

United States' Response: The United States disputes Roxane's characterization of the date shown in the report at Tab 124. The United States does not dispute that it has approved Medicaid program reimbursement systems based on an EAC that includes the lower of AWP minus a variety of percentages, and WAC plus a variety of percentages.

76. CMS also continued to approve state plan amendments ("SPA") that proposed AWP-based formulas that would result in payments higher than actual acquisition costs. For example, HCFA approved a 2002 Kentucky SPA to change reimbursement from AWP-10% to AWP-12% despite Kentucky supporting its submission with a Myers & Stauffer report showing that pharmacies acquired multi-source drugs at AWP-34.1% (without a FUL) to 81.4% (with a FUL). (Tab 125, HHD087-3742 - 3790, Aug. 12, 2002 CMS Letter Approving Kentucky State Plan Amendment 02-04 and Accompanying Documents.)

United States' Response: The United States does not dispute the facts in Paragraph 76, but does dispute the characterization by Roxane and materiality of the documents cited. The statements in the first sentence of this paragraph are irrelevant as in 2002 Kentucky was required to base its reimbursement formula as set forth in 42 C.F.R. § 447.331. The United States does not contend that Kentucky is required to base its Medicaid reimbursement on actual acquisition cost. Further, as stated by Deidre Duzor, Director of CMS's Pharmacy Division, CMS does not "dictate to the states," and "the consequence of disapproval could be greater overpayments." (Fauci Exhibit 179 (3/26/2008 Deidre Duzor Dep.), at 644). The states increasing the percentage of deduction from AWP were "moving in the right direction and

saving the state and federal government money by doing so." (*Id.*) If CMS had not approved such amendments, the states would be paying at the higher reimbursement rates in the unamended state plan. (*Id.*, at 645:1 - 645:11, 647:6 - 647:9)

77. As Deirdre Duzor, the Director of CMS's Medicaid Pharmacy Division, testified, CMS continued to approve state plan amendments that reimbursed at AWP-20% despite its awareness that average acquisition cost for generics was AWP-60%:

> Q. Okay. I will rephrase the question. If, in fact, you have reports from the OIG indicating that generic drugs are available at AWP minus 60 percent on average across the board for all generics, why do you approve plans that allow reimbursement for generics at AWP minus 15 or minus 20?
>
> * * *
>
> THE WITNESS: Because they're moving in the right direction. They're reducing pharmacy reimbursement and saving the states and the federal government money by doing so.
>
> BY MR. MERKL: Q. So you are aware, then, that the pharmaciesare making money on that difference between what they're acquiring the drug for and what they're reimbursing it at in the case of generics?
>
> * * *
>
> THE WITNESS: Yes. Based upon the OIG reports, we are aware of that.

(Tab 21, 3-26-08 Duzor Dep. 645-47.)

United States' Response: Roxane has correctly, but selectively, quoted from the testimony of Ms. Duzor; the entirety of the testimony referenced is the best evidence of its contents.

78. In addition, once CMS approves a state plan, the state plan remains in effect and CMS does not review it again "until the state chooses to change its state plan." (Tab 48, 3-27-08 Smith Dep. 515-18.)

United States' Response: The United States does not dispute the statements in Paragraph 78.

79. Moreover, in its 2008 report, "Review of the Relationship Between Medicare Part D Payments to Local, Community Pharmacies and the Pharmacies' Drug Acquisition Costs," OIG

concluded that pharmacies' acquisition costs of generic drugs were AWP-73%. (Tab 126, OIG Jan. 2008, "Review of the Relationship Between Medicare Part D Payments to Local, Community Pharmacies and the Pharmacies' Drug Acquisition Costs," A-06-07-00107, Table 2, at 6 ("Jan. 2008 OIG Report").) Under Plaintiffs' methodology, this translates to a 270% spread. CMS responded to the report:

- Although CMS indicated that it understood that the OIG report "found that the **percentage differences between Part D payments and drug acquisition costs** were more than **nine times higher** for generic drugs than for brand-name drugs," it **"fully encourage[d]** the use of generic drugs since their use provides good value to both the beneficiary and the taxpayer, and we note that incentives are aligned to encourage the promotion of generics by community pharmacies." (*Id.* at Appendix G, p. 1(emphasis added).)

United States' Response: The United States does not dispute the contents of the January 2008 OIG report. Roxane has correctly, but selectively, quoted from the report entitled "Review of the Relationship Between Medicare Part D Payments to Local Community Pharmacies and the Pharmacies' Drug Acquisition Costs." The entirety of the document referenced is the best evidence of its content.

VIII. INFORMATION REGARDING WIDESPREAD DISCOUNTS OFF AWP: IPRATROPIUM BROMIDE AND NEBULIZER DRUGS

80. In February 1996, the OIG published a report concerning the extent to which Medicare was overpaying for three nebulizer products, similar to Albuterol Sulphate and ipratropium bromide. (Tab 127, Abbott Ex. 33, OIG Feb. 1996, *Medicare Payments for Nebulizer Drugs* (Feb. 1996 OIG Report).) In its report, the OIG stated and concluded the following:

- "Medicare allowed a higher price to drug suppliers for two of the three drugs reviewed because of the manner in which it used the AWP to determine the drug price." At the time, Medicare was still using the full, undiscounted, published AWP as the basis for calculating provider reimbursement. (*Id*. 2, 6.)

- OIG recommended that "HCFA reexamine its Medicare drug reimbursement methodologies with a goal of reducing payments as appropriate." (*Id.* 11.)

- Had Medicare reimbursed providers based on a discounted AWP—as twenty-six state Medicaid programs were already doing—Medicare would have saved millions of dollars. (*Id*. 13.)

United States' Response: The United States disputes the first sentence of this paragraph in that it does not accurately paraphrase the February 1996 OIG report which states that OIG selected "the three nebulizer drugs with the highest allowed amounts (1) Albuterol sulfate 0.083%... (2) Metaproterenol Oternol Sulfate 0.4% and (3) Metapretenol Sulfate 0.6%", at p.4. These drugs are not at issue in this case. Roxane correctly, but selectively, quotes from the 1996 OIG report; the entirety of the document referenced is the best evidence of its content. The United States disputes the materiality of the report, since Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18)

81. David Tawes, Director of the Medicare and Medicaid Drug Pricing Unit in the Philadelphia office of the OIG Office of Evaluation and Investigations, was aware of spreads on ipratropium bromide:

- Among the catalog prices reported by Ven-A-Care in 1997, the OIG received prices for ipratropium bromide. (Tab 52, 12-13-07 Tawes Dep. 707; Tab 128, Roxane Ex. 17, Conversion from NDC Amounts to HCPCS Amounts.)

- The OIG considered including ipratropium bromide in its 1997 report on excessivedrug reimbursement, and documents show that at that time the OIG performedcalculations to determine the spreads between the Ven-A-Care prices and the amountsbeing reimbursed by Medicare. (Tab 52, 12-13-07 Tawes Dep. 697; Tab 128, RoxaneEx. 17, Conversion from NDC Amounts to HCPCS Amounts.)

United States' Response: The United States disputes that the statements in this paragraph are accurate. Mr. Tawes in 1997 was a program analyst and not Director of the Medicare and

Medicaid Drug Program Unit of the Philadelphia office of the OIG Office of Evaluations and Investigations. (Fauci Exhibit 178 (4/24/2007 David Tawes Dep.), at 31-32). He did not work on the report about which he was questioned. (Tab 52, at 705) The documents attached by Roxane as exhibits to this paragraph do not contain the information stated. Tab 128 is headed "Conversion from NDC amounts" to HPCSs amounts and compares FSS prices, not VAC prices, for specified drugs not including ipratropium, to estimated HCPC's prices.

82. Based on information that albuterol payments under Medicare were substantially higher than acquisition costs, in 1998 HCFA attempted to use its inherent reasonableness authority to reduce payments for albuterol by 11 percent. Congress rejected the reduction and also suspended the inherent reasonableness authority in 1999 until further investigation by the GAO. (Tab 111 at CRS-5, CRS Memo, August 2001; Tab 114, Abbott Ex. 94, Jan. 2001 OIG Report, *Medicare Reimbursement for Prescription Drugs*, at 2, Appendix F, p. 2.)

United States' Response: The United States disputes that the statements in this paragraph accurately paraphrase the documents cited. The CRS memo of August 2001 notes that HCFA "reportedly" attempted to use its inherent reasonableness authority and "reportedly" targeted Albuterol for an 11% reduction. The January 2001 OIG report states that "before any of the lower prices could be implemented Congress suspended the use of inherent reasonableness through a provision of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999. This provision required the General Accounting Office (GAO) to complete a study of the potential effects of using inherent reasonableness measures before HCFA could invoke the authority." By way of further answer, the documents referenced are the best evidence of their contents. Further, Albuterol is not at issue in this case.

83. In November 1998, the OIG issued a report entitled "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs." In its report, the OIG stated and concluded the following:

- AWPs for ipratropium bromide were, on average, 155% higher than the prices at which that drug could be purchased by government providers. (Tab 129, Roxane Ex. 159, OIG Nov. 1998, *Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs* 7, 13. (Nov. 1998 OIG Report.)

United States' Response: The United States does not dispute that in November 1998 the OIG issued a report entitled "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs," but does dispute that Roxane has accurately paraphrased from the report since the included language is not contained in the report. The entirety of the document referenced is the best evidence of its contents. The United Sates disputes the materiality of the report to Roxane's liability under the FCA, since Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18)

84. By 1998, OIG Regional Inspector General Robert Vito was "aware that ipratropium bromide represented potential savings to the Medicare program." (Tab 58, 12-2-08 Vito Dep. 1295-96.)

United States' Response: The United States does not dispute the statements in this paragraph except to state that Mr. Vito testified that the date was "whenever it [the report] was issued."

85. Representative Stark's September 1999 press release, "Drug Utilization Soars as Profits Soar," also included the following statements and conclusions specific to ipratropium bromide:

- "In the last several years, the cost of ipratropium bromide to druggists and doctors has dropped by 50%, but the amount per unit that Medicare pays for this drug has stayed the same." (Tab 130, 9-1-99 Stark Press Release "Drug Utilization Soars as Profits Soar" (9-1-99 Stark Press Release).)

- A table comparing the average Medicare reimbursement for ipratropium bromide with the cost to the wholesaler for that drug for the years 1996 to 1999 showed that the spreads for ipratropium bromide increased progressively and dramatically over the years as follows: 15% in 1996; 63% in 1997; 96% in 1998; and 10% in 1999. (*Id*.)

United States' Response: Roxane has correctly, but selectively, quoted from Congressman Stark's press release of September 1, 1999. The entirety of the document referenced is the best evidence of its contents. The United Sates disputes the materiality of the press release to Roxane's liability under the FCA, since there is no evidence that responsible Roxane official read such documents at the time; Roxane's designated 30(b)(6) witness testified that Roxane did not rely on such information in setting AWPs for Roxane drugs, (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18), and the press release does not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPs.

86. The OIG obtained pricing information related to ipratropium bromide from Ven-A-Care by early 2001 that it used to compile its 2001 report on ipratropium bromide. (Tab 58, 12-2-08 Vito Dep. 1315.)

United States' Response: The United States does not dispute this paragraph except that Mr. Vito testified the that the pricing information referenced was used to compile the 2002 report. (Tab 58, at 1314:15 - 1314:16)

87. In September 2001, the United States General Accounting Office ("GAO") issued a report to Congress entitled "Payment for Covered Outpatient Drugs Exceed Providers' Costs." (Tab 131, Abbott Ex. 186, Sept. 2001 GAO Report). The report, which was commissioned by Congress, examined revised prescription drug reimbursement methodologies under Medicare and Medicaid. In its report, the GAO stated and concluded the following:

- "[T]wo drugs used with durable medical equipment had discounts of 78% and 85%, equating to 'spreads' of 355% and 567%." *In re Pharm. Indus. AWP Litig.*, 491 F. Supp. 2d at 43 (citing Report to Congressional Committees, Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost 2001 ("GAO Report"), at 4). The drug with

the 78% discount and the 355% spread was ipratropium bromide. (*Id*. 4.)

United States' Response: The United States disputes that Roxane has accurately quoted from the September 2001 GAO report "Payment for Covered Outpatient Drugs Exceed Providers' Costs" but rather from the case cited. The report made no mention of "equating to 'spreads of 355% & 567%'" or a 355% spread for ipatropium. The entirety of the document referenced is the best evidence of its content. The United States disputes the materiality of the report, since Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices, (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) and the report does not refer to any government policy, practice or statement approving Roxane's reporting of inflated AWPs.

88. Former HCFA/CMS Administrator Thomas A. Scully was aware of "mind blowingly big margins" for ipratropium bromide. (Tab 46, 5-15-07 Scully Dep. 255.)

United States' Response: The United States does not dispute that Mr. Scully made this statement. Mr. Scully also stated that there was evidence of manufacturers "gaming the system." (Fauci Exhibit 181 (5/15/2007 Thomas Scully Dep.), at 328-329) By way of further response, there is no evidence of any formal policy statement demonstrating that a federal official approved of these margins on ipatropium. Further there is no evidence that Roxane ever communicated to the United States its practice of reporting AWPs that are not an actual average wholesale prices of Roxane drugs. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 140:22, 141:1 -141:4; 207:9 - 207:18, 208:1 - 208:6; 218:1 - 218:10)

89. In March 2002, the OIG issued a report to CMS entitled *Excessive Medicare Reimbursement for Ipratropium Bromide*. (Tab 132, Roxane Ex. 1, 2002 OIG Report, *Excessive Medicare Reimbursement for Ipratropium Bromide*, (Mar. 2002 OIG Report).) In its report, the OIG specifically noted CMS's "numerous attempts" to "lower reimbursement amounts for prescription drugs," and stated that its findings "illustrate that Medicare pays too much for ipratropium bromide." (*Id.* at iii.) The report also noted that the OIG understood that "unlike most drugs covered by Medicare, ipratropium bromide is usually provided by suppliers rather than administered by physicians. *These suppliers obviously need to make a profit* from the products they provide, yet the spread between what Medicare reimburses for ipratropium bromide and the price at which suppliers are able to purchase the drug is significant." (*Id.* (emphasis added).) Compared to drugs purchased form wholesalers, this translates to a spread of 300 percent under Plaintiffs' methodology. (*Id.* at 19.)

United States' Response: Roxane has paraphrased and selectively quoted from the March 2002 OIG report "Excessive Medicare Reimbursement for Ipratropium Bromide;" the report does not contain the language of the last sentence of this paragraph. The entirety of the document referenced is the best evidence of its content. The United States disputes the materiality of the report, since Roxane's 30(b)(6) designee testified that in setting its AWPs Roxane did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18)

90. In 1996, Ven-A-Care began tracking prices of ipratropium bromide and Albuterol. (Tab 133, Roxane Ex. 90, p. 45 (IB Chart)); (Tab 34, 12-9-08 Jones 30(b)(6) Dep. 1140-45.) Dey and Roxane were the sole manufacturers of generic Ipratropium Bromide from 1996 through the late 1990s. (Tab 34, 12-9-08 Jones 30(b)(6) Dep. 1144-45.)

United States' Response: The United States disputes that Roxane has accurately paraphrased the deposition testimony cited. Mr. Jones testified that "We had prices early on for Ipratropium, but we really didn't see the blooming of the spread until later on the late 90's." (Tab 34, at 1144:7 - 1144:11) The entirety of the testimony referenced is the best evidence of its content.

IX. THE GOVERNMENT RECEIVED A WORKING DATABASE THAT SHOWED THE "SPREADS" FOR ALL OF ROXANE'S DRUGS

91. Ven-A-Care also provided the federal Government with a working database provided by the McKesson wholesaler called Econolink that included the regular and contract prices for every Roxane NDC drug at issue in this case (except the Novaplus ipratropium bromide NDCs). (Tab 38, 6-19-09 Lockwood Dep. 95-96.)

United States' Response: Undisputed. By way of further answer, the Econolink database provided regular and contract prices for the thousands of drugs carried by McKesson. (Tab 38, at 19)

92. The Econolink database was accessible to McKesson's customers, including Ven-A-Care. (*Id.* 18-21.)

United States' Response: Undisputed. By way of further answer, the witness testified that "at some point . . . they were transitioning what I assume are all of their McKesson pharmacies, whatever their class of trade might be, from a hard copy catalog to an electronic system" (Tab 38, at 21)

93. In addition to the working database on the laptop computer, Ven-A-Care provided eleven updates, or database "snapshots" from the Econolink database to the Government, on the following dates: October 23, 2000; December 12, 2000; February 22, 2001; April 20, 2001; June 19, 2001; August 9, 2001; November 12, 2001; January 28, 2002; March 10, 2002; May 8, 2002; and June 25, 2002. (Tab 38, 6-19-09 Lockwood Dep. 15-16, 24-27, 31; Tab 134, Roxane Ex. 226, October 23, 2000 Econolink short-form printout; Tab 135, Roxane Ex. 231, December 12, 2000 Econolink short-form printout; *see also* Tab 136, Roxane Ex. 223, Feb. 24, 2009 e-mail from Alison Simon to Eric Gortner re McKesson Econolink databases.)

United States' Response: Disputed. The United States disputes the statements in this paragraph to the extent that Ven-A-Care did not always provide the updates from the Econolink database on the dates they were printed. For example, Dr. Lockwood testified that the October 23, 2000 snapshot and the December 12, 2000 snapshot were provided at a meeting in January 2001. (Tab 38, at 17, 18, 32-33) The United States does not dispute that the listed updates were

provided by Ven A Care to the Department of Justice shortly after their respective dates.

94. The Econolink database contained pricing data for NDCs, including AWP, the wholesaler price, and any contract price that applied. (Tab 38, 6-19-09 Lockwood Dep. 19.) In addition, it "would automatically calculate what it termed the spread"—it "actually . . . would show you the spread and it was labeled spread between the AWP and the acquisition cost that was calculated by the software." (Tab 38, 6-19-09 Lockwood Dep. 78-79; Tab 37, 7-23-08 Lockwood Dep. 1109, 1120.)

United States' Response: The first sentence of this paragraph is disputed as Dr. Lockwood testified that the Econolink database contained AWP, any applicable contract price and "McKesson list prices." (Tab 38, at 78-79) The second sentence of the paragraph is taken out of context as the testimony continued, "It would show you the difference between the contract price and the AWP or the best price and the AWP." It would "give you a spread dollar difference and they called it the spread" (Tab 37, at 1109:6 - 1109:8, 1110:21-1110:22)

95. Prior to 2001, the database showed spreads of over 100%, and in several cases over 1,000%, for all of Roxane's drugs at issue in this case. (Tab 38, 6-19-09 Lockwood Dep. 90-95.) For example, the short form printout of Roxane drugs in the Econolink database from December 12, 2000, showed the following range of spreads, as calculated under Plaintiffs' methodology for the nine drugs at issue here:

- Oramorph NDC 00054-4790-29: AWP of $413.20 and a contract price of $198.74—a **spread of 108%**
- Roxicodone NDC 00054-4657-25: AWP of $31.04 and a contract price of $13.44—a **spread of 131%**
- Azathioprine NDC 00054-4084-25: AWP of $131.08 and a contract price of $43.72—a **spread of 200%**
- Hydromorphone NDC 00054-8394-24: AWP of $71.71 and a contract price of $22.58—a **spread of 218%**
- Sodium Polystyrene NDC 00054-8816-11: AWP of $86.50 and a contract price of $25.56—a **spread of 283%**
- Ipratropium bromide NDC 00054-8402-13: AWP of $52.80 and a contract price of $10.86—a **spread of 386%**

- Roxanol NDC 00054-3751-50: AWP of $77.96 and a contract price of $11.72—a **spread of 565%**

- Diclofenac Sodium NDC 00054-4222-31: AWP of $1,025.25 and a contract price of $152.19—a **spread of 574%**

- Furosemide NDC 00054-4297-31: AWP of $139.90 and a contract price of $8.84—a **spread of 1,483%**

(Tab 135, Roxane Ex. 231, December 12, 2000 Econolink short-form printout.)

United States' Response: The United States disputes that the short form printout from December 12, 2000, shows spreads to the extent that the printout does not contain a spread column or screen. It is further disputed that the NDCs for Oramorph, Roxicodone, hydromorphone or diclofenac sodium listed in this paragraph are at issue in this case.

X. GENERAL ROXANE BACKGROUND

96. In April 2005, Roxane Laboratories, Inc., a Delaware corporation, changed its name to Boehringer Ingelheim Roxane, Inc. ("BIRI"). (Roxane Answer to First Am. Compl. at 1 n.1) BIRI remains a Delaware corporation. (*Id.*) BIRI continues to manufacture pharmaceutical products. (*Id.*) Also in April 2005, a new entity, Roxane Laboratories, Inc., a Nevada corporation, was incorporated. (*Id.*) As of that time, the new Nevada corporation ("Roxane Nevada") assumed responsibilities for sales and marketing of pharmaceutical products sold under the Roxane tradename. (*Id.*) For the purpose of this Statement of Facts, all statements referencing "Roxane" will be meant to reference the company BIRI for the time period until April 2005 and Roxane Nevada for the time period after April 2005.

United States' Response: Undisputed.

97. Roxane has been a manufacturer and seller of predominantly generic pharmaceuticals in the United States. (Tab 65, 5-9-07 Waterer Dep. 36; Tab 14, 5-30-07 DeCapua Dep. 15-16) Currently, the Roxane product line consists of roughly 400-500 NDCs. (Tab 14, 5-30-07 DeCapua Dep. 167)

United States' Response: The United States does not dispute that Roxane markets and sells primarily multi-source pharmaceuticals. Further answering, Roxane markets several of its multi-source pharmaceuticals as "branded generics" meaning that Roxane assigned the product a brand

name and marketed it according to a branded marketing strategy. (Fauci Exhibit 2 (1/27/2005 Sheldon Berkle Dep.), at 129:1 - 129:20) Roxane also manufactures branded and generic products, including branded products marketed by its sister company (BIPI). (Fauci Exhibit 96 (2/26/2009 James McIntyre 30(b)(6) Dep.), at 80:16 - 81:16)

98. Roxane's products are almost all self-administered drugs, taken by the patient in tablet, capsule, or liquid form, including the drugs at issue in this case. (Tab 65, 5-9-07 Waterer Dep. 36-37; Tab 5, 12-12-08 Carr-Hall Dep. 53; Tab 41, 3-8-05 Paoletti Dep. 474; Tab 137, United States' First Am. Compl. Ex. A)

United States' Response: Undisputed.

XI. ROXANE'S UNDERSTANDING OF AND PRACTICES REGARDING AWP

99. Roxane understood AWP to be a reference point that is generally tied to the branded version of a multisource drug. (Tab 65, 5-9-07 Waterer Dep. 69, 93-94) At launch AWP is generally set at 10% below the corresponding brand's AWP. (*Id.*) Roxane understood this to be the industry standard. (Tab 65, 5-11-07 Waterer Dep. 604; Tab 66, 12-12-08 Waterer Dep. 33-34)

United States' Response: Disputed. Roxane knew that its reported AWPs were used by the Medicare and Medicaid programs to determine reimbursement. (*See, e.g.,* Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 93:16 - 93:22, 129:11 - 130:1, 244:14 - 245:19; *see also* US-BR-SF, ¶ 116-118) Federal regulations require that Medicaid programs' reimbursement for drugs not subject to Federal Upper Limits not exceed, in the aggregate, the "estimated acquisition cost" of a drug, which is defined as the "agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.301 and § 447.331.

Roxane offers no evidence to support a finding that manufacturers of multi-source drugs set AWPs according to any consistent standard. In fact, during the relevant time frame it was not

unusual for generic manufacturers to set AWPs at the time of launch that were 20% to 25% below the brand AWP. (Fauci Exhibit 136 (Declaration of Steven Schondelmeyer) ¶¶ 11-16) The United States does not dispute that Roxane's stated practice was to set the AWP for some of its multi-source products at 10% below the corresponding brand's AWP at the time of launch. To the extent this practice was an "industry standard," however, it was not known at Roxane until 1996, following Judy Waterer joining Roxane's Marketing department. According to Ms. Waterer:

> There was a – there's a general rule of thumb in generics that you peg your AWP at ten percent under brand. You see it very, very commonly. When I came on board with Roxane, they didn't know that.

(Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 434:18 - 434:22; Fauci Exhibit 5 (1/31/2003 Edward Tupa Dep.), at 67:19 - 68:1) For certain of the Subject Drugs (e.g., hydromorphone) the AWP was *not* set at 10% below the corresponding brand's AWP at the time of launch. (*See, e.g.* Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 588:13 - 588:22) When Roxane did set its AWP for a multi-source product at 10% below the brand AWP, it did so deliberately and in order to increase reimbursement for its products and thereby give its products a "competitive advantage." (Fauci Exhibit 26) For example, in or around October 1996, Roxane increased the AWP for metaproterenol (which is not a Subject Drug). (*Id.*) An internal memorandum noted that raising the AWP to 10% off the brand would afford Roxane with a "competitive advantage." (*Id.*)

When launching a product into an "existing market," Roxane set the AWP at a level comparable to competitors' AWPs. (Fauci Exhibit 19 (9/30/2005 Leslie Paoletti Dep.), at 26:15 - 27:14) In addition, for some multi-source products marketed by Roxane as brands or branded

generics, Roxane set the AWP at a markup from the WAC. (Fauci Exhibit 112 (6/25/2002 Richard Feldman Dep.), at 44:15 - 46:9) Roxane was aware that the AWPs for many branded products were typically set at a 16 and 2/3% or 20% mark-up from WAC. (*See, e.g.* Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.); at 477:5 - 478:24; Fauci Exhibit 113 (12/3/2004 James King Dep.); at 197:25 - 198:24; (Fauci Exhibit 128 (4/3/2003 James Rowenhorst Dep.), at 158:22 - 159:7; (Fauci Exhibit 137))

Further answering, Roxane has cited no evidence that any government agencies approved of generic AWPs being set at 10% below the brand AWP.

100. Roxane's understanding of the industry standard came from (1) general common knowledge, (2) publicly-available information such as the AWPs of Roxane's competitors, and (3) Roxane employee's contacts with everyone in the industry that they worked with. (Tab 66, 12-12-08 Waterer Dep. 27-28, 38-40)

United States' Response: Disputed. Roxane considered reimbursement spreads when setting and reporting prices (including AWPs) for its products. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 66:19 - 67:16) In setting AWPs for its products Roxane did not review or consider federal regulations relating to Medicare and Medicaid reimbursement. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 160:10 - 160:22, 165:20 - 167:14; Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 238:19 - 239:10, 283:4 - 283:19) Likewise, in setting its AWPs, Roxane did not review, consider or rely upon any reports published by the federal government as indications that the federal government was aware or approved of Roxane's price reporting practices. (Fauci Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 142:20 - 144:3, 208:8 - 208:18) Roxane acknowledges that the federal government never informed Roxane that it approved of Roxane's AWPs. *(Id.)*

101. Roxane never intended its AWPs to be used as or to represent an actual average of

wholesale prices to customers, as that was not the meaning of AWP as used in the industry. (*Id.*) 24-25) Roxane's AWPs also did not bear a predictable relationship to the prices that Roxane's drugs were sold in the marketplace, and nobody in the industry thought that they did. (*Id.* 26-28 ("(W)e've never heard it described as anything else. In many, many, many years in the industry, it's been AWP has had a recognized definition or meaning that did not mean it was an actual, some kind of calculated average of prices in the marketplace …. "))

United States' Response: Disputed. (*See supra* United States' Responses to Paragraphs 99 - 100) Further answering, Roxane was aware that many third party payors, including Medicaid, used First Data Bank to obtain AWPs and that such AWPs were used by Medicaid programs in setting reimbursement. (*See, e.g.,* Fauci Exhibit 112 (6/25/2002 Richard Feldman Dep.) at 88:2 - 88:12) Roxane was aware that, at various times, First Data Bank defined AWP as follows:

> AWP is the average wholesale price. That is, AWP is the average of the prices changed by the national drug wholesalers for a given product (NDC). The operative word is average. AWP was developed to provide a price which all parties could agree upon for electronic pricing to be possible.

(Fauci Exhibit 117) A "Reimbursement Background" memorandum distributed to Roxane's palliative care sales force in September 2000 described AWPs as follows:

> Wholesalers marked up their acquisition cost by 20% - 25% for resale to their pharmacy customers. These resale prices were referred to as Average Wholesale Prices (AWP) and *were meant to reflect an average of suggested list prices that wholesalers charged various customer outlets (e.g., retail pharmacies and physician offices).*

(Fauci Exhibit 101, at Paoletti 20751 - 52 (emphasis supplied)) The memorandum also noted that AWPs were "commonly used by retailers and others who dispense medications as the basis for many pricing decisions" and that "*the AWP is often used as a surrogate for actual prices* when studying prescription price trends." (*Id.*, at Paoletti 20756 (emphasis supplied))

The United States further notes that Roxane never communicated to the Medicare or Medicaid programs that its AWPs did not have a predictable relationship to sales prices. (Fauci

Exhibit 130 (12/12/2008 Judith Waterer 30(b)(6) Dep.), at 206:6 - 208:6, 218:2 - 218:19; Fauci Exhibit 27 (5/9/2007 Judith Waterer 30(b)(6) Dep.), at 180:4 - 180:18; Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 216:1 - 217:13) In 1999, when Thomas Russillo (Director of Multi-Source Marketing at Roxane and President at Roxane's corporate affiliate, Bedford Laboratories) was asked by Congressman Thomas Bliely to define AWP as that term was used by Bedford Laboratories, the response stated: "Given its pricing terminology and practice, the definitions of the terms 'average' and 'wholesale' are the standard dictionary definitions." (Fauci Exhibit 138)

The United States does not dispute that Roxane's AWPs for the drugs at issue in this litigation did not bear a predictable relationship to prices in the marketplace.

102. As the Government was an important participant in the industry, Roxane had no reason to believe that it did not have the same understanding of AWP as everyone else in the industry. (*Id.* 33-34) On the contrary, Roxane had every reason to believe that the government knew very well that AWP was not a defined actual average wholesale price, based the following facts:

- AWP is a generally understood term in the industry in which the Government participates. (*Id.* 137-39 ("the government would have every reason to know that that price was not defined in the industry or in any general practice as some kind of an actual average of wholesale prices."))

- Roxane provides the federal government with Average Manufacturer Prices ("AMPs") for its products and the Government can easily see the difference between the AWPs published for its products and the AMPs Roxane provides. (*Id.* 172-73) (discussed more fully below)

- Roxane understood that to the extent the government and other third party payors tied reimbursement to AWP, it was always set at a discount off of AWP. Roxane believed those discounts ranged from 10 to 40 percent off of AWP. Thus the Government and third party payors could not have believed AWP was an actual acquisition cost. (*Id.* 28-29 ("it would be irrational to think that anybody doing that reimbursement would think that's the price that a customer paid for it, that they would be willing to accept reimbursement way below what their acquisition cost was"))

- Roxane and other manufacturers generally set their AWPs when a product launched; a time when there was no historical pricing or sales off of which an average of actual wholesale prices could be calculated and reported. (*Id.* 236-37)

- Historically, when the Government has wanted an average or a specific number calculated and reported, it generally provides a formula and guidance on how to calculate that figure, as it did with AMP and ASP. Otherwise, without such guidance, there are too many variables and questions about what should be included and how the figure should be calculated. The Government has never provided a formula or guidance on how to calculate AWP. (*Id.* 145)

United States' Response: Disputed. (*See supra* United States' Responses to Paragraphs 99-101) Further answering, the "Government" is not a "participant" in the pharmaceutical industry. In addition, Roxane has offered no evidence to establish that there was any understanding "in the industry" that AWPs did not accurately reflect an average of wholesale prices to customers, or that AWPs did not bear a predictable relationship to the prices at which drugs were sold in the marketplace. Responsible government officials testified that they believed reported AWPs bore a predictable relationship to sales prices. (*See, e.g.*, Fauci Exhibit 139 (5/4/2007 Bruce Vladeck Dep.), at 138:21 - 140:6, 154:4 - 154:21, 156; Fauci Exhibit 140 (12/5/2007 Nancy DeParle Dep.), at 399:20 - 400:18, 410:21 - 411:14, 638:20 - 639:6) Further, numerous reports and publications by the Department of Health and Human Services, Office of Inspector General consistently referred to AWPs which exceeded sales prices to customers as "inflated" and resulting in "overpayments" by the Medicare and Medicaid programs. (*See, e.g.* Tab 71, at 1, 9) Moreover, personnel at Roxane were aware that federal officials regarded AWPs that did not reflect sales prices to customers as "artificially inflated." (Fauci Exhibit 132)

103. Roxane does ***not*** have an understanding that Medicaid programs seek to determine and estimate an acquisition cost as part of their reimbursement for reimbursing pharmacists. (*Id.* 30)

United States' Response: Disputed. As a participant in the Medicaid program, Roxane was

required to be familiar with legal requirements, standards, and procedures of the Medicaid program, including those applicable to reimbursement. Those requirements included that Medicaid programs' reimbursement for drugs not subject to Federal Upper Limits exceed their estimated acquisition costs. (*See supra* United States' Response to Paragraph 99)

104. Roxane provides AWPs to the pricing compendia, such as First DataBank, because its pharmacy customers require it. (Tab 65, 5-9-07 Waterer Dep. 63-64)

United States' Response: Undisputed.

105. If Roxane is late to the market and there are many other generic competitors, Roxane may set its AWP at launch at or around the same level of the generic competitors instead of at the brand AWP minus 10%. (Tab 66, 12-12-08 Waterer Dep. 41-42)

United States' Response: Undisputed.

106. After Roxane sets an AWP for a drug, it generally does not change its AWP. Roxane understood that industry practice for generic products was that after launch the AWP was not typically changed. (*Id.* 94-95) Two exceptions to this rule are: (1) when a Roxane drug becomes a sole-source drug, Roxane may increase all of its prices across the board, including the AWP; and (2) when a customer complains and points out that Roxane's AWP is significantly lower than its competitors. (Tab 65, 5-9-07 Waterer Dep. 74-76)

United States' Response: Disputed. Roxane offers no evidence to support a finding that there was any common industry practice regarding the setting of AWPs for multi-source products, nor that Roxane followed any consistent practice with regard to its own AWPs. Further answering, Roxane raised AWPs for some multi-source products (e.g., azathioprine) following launch because competitors had increased their AWPs, and Roxane wanted to "catch up" to avoid being competitively "disadvantaged." (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 140:14 - 142:1, 252:9 - 253:22; *see also* US-BR-SF, ¶ 64-73) Further answering, Roxane increased its AWPs in order to increase reimbursement for its products and thereby gain a "competitive advantage." (Fauci Exhibit 26; Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 183:7 -

183:10, 315:8 - 316:2)

XII. ROXANE'S UNDERSTANDING OF AND PRACTICES REGARDING WAC

107. Roxane's WAC was not a net number; rather it was a list invoice price that Roxane charged wholesalers. (Tab 65, 5-9-07 Waterer Dep. 72-73) Roxane believed this to be the industry understanding and practice regarding WAC. (Tab 65, 5-11-07 Waterer Dep. 660)

United States' Response: Disputed. For various of its products and for various time periods, Roxane reported WACs to pricing compendia which were used by state Medicaid programs to estimate the prices generally and currently paid for drugs. (*See supra* United States' Response to Paragraph 99)

Further answering, Roxane offers no evidence of an "industry understanding and practice" that WAC was "not a net number" or that WAC was a "list invoice price." On the contrary, numerous publications have referred to WAC as a net price. For example, the 1994 First Data Bank National Drug Data File User Manual described the "Wholesale Unit Price" or "WHN" as the manufacturer's "wholesale *net* unit price[.]" (Fauci Exhibit 141) Likewise, a 1994 article published by HCFA (now CMS) in "Health Care Financing Review" defined WAC as "the wholesaler's net payment made to purchase a drug product from the manufacturer, net of purchasing allowances and discounts." (Fauci Exhibit 142)

108. Federal government reports as early as 1994 confirmed the Federal government's acknowledgment of this industry understanding that WAC does not include prompt pay or other discounts, rebates, or reductions in price. (Tab 88, U.S. Gen. Accounting Office, *Prescription Drugs: Companies Typically Charge More in the United States Than in the United Kingdom,* Jan. 1994) (confirming that, in 1994, it was generally understood that WAC does not capture manufacturers' discounts and price reductions to certain buyers)) Congress codified this industry understanding in the Medicare Modernization Act of 2003 where WAC is defined as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price …." (42 U.S.C. § 1395w-3a(c)(6)(B))

United States' Response: Disputed. Further answering, Roxane misrepresents the content and

significance of the referenced GAO report. At page 1 of the report, the GAO notes that "[o]ur study focuses on factory prices, brand-name drugs, and *the market segment in which retail pharmacies generally do not receive manufacturers' discounts*." (Tab 88, at 1 (emphasis added)) The GAO made clear that it used WAC as the basis for its comparison of U.S. and U.K. prices because WAC was the factory price for the "undiscounted market segment" (i.e., the market segment involving retail outlets "that do not negotiate substantial discounts from drug companies.") (*Id.*, at 17) The GAO explained: "The WAC represents the factory price for most of the outpatient prescription drug market: the 55% of that market served by wholesalers who do not receive discounts from manufacturers." (*Id.*, at 18) Nothing in the referenced report supports the view that WAC does not include discounts, rebates or reductions in price, where such discounts, rebates or reductions in price are commonly negotiated from drug companies.

The United States admits that the Medicare Modernization Act of 2003 ("MMA") defined WAC as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price …" The United States disputes that this definition codified an "industry understanding" that WAC was not a net price, and the United State disputes that there was any such industry understanding. (*See supra* United States' Response to Paragraph 107)

109. Roxane set the WACs for its drugs in accordance with this industry standard as the list or invoice price that a wholesaler pays Roxane. (Tab 65, 5-11-07 Waterer Dep. 615-16) This amount initially invoiced by Roxane may be reduced for a particular wholesaler if the wholesaler qualifies for a prompt pay discount (typically 2%) or other occasional discounts such as an additional discount when a new product is launched. (*Id*. 616-17; Tab 62, 10-24-01 Waterer Dep. 178)

United States' Response: The United States disputes that there is an "industry standard" that WAC is the list or invoice price to a wholesaler. (*See supra* United States' Responses to

Paragraphs 107-08) Further answering, the United States disputes Roxane's characterization of the nature of WAC in the context of direct sales to wholesalers. Roxane contract documents show that Roxane typically entered into contracts with wholesalers for sales of Roxane products at contract prices significantly below WAC. For example, in a contract between Roxane and the wholesaler "The F. Dohmen Co.," effective December 1, 1998 through December 31, 1999, Roxane agreed to sell various products at contract prices well below WAC, with additional rebates lowering the prices still further. (Fauci Exhibit 143) The following table compares the actual contract prices with the published WACs (for the first two quarters of 1999) for the ipratropium bromide products:

NDC	**Product Description**	**Contract price**	**Rebate**	**FDB WAC**
00054-8402-11	Ipratropium Bromide, 25s	$15.56	15%	$25.50
00054-8402-13	Ipratropium Bromide, 30s	$18.67	15%	$30.60
00054-8402-21	Azathioprine Tablets, 50mg	$83.25	10%	$103.54

(*Id.;* Fauci Exhibit 3 (Platt Decl.), Summary A1) Roxane's WAC was not a "price" but a fiction.

110. The amount ultimately paid by a particular wholesaler to Roxane will also depend on whether Roxane has a pre-negotiated contract price with the provider purchasing the drug from the wholesaler. This contract price is generally lower than WAC. (Tab 65, 5-9-07 Waterer 150-51) If Roxane does not have a pre-negotiated contract price with the provider, then the wholesaler sells the product to the provider at a price that, presumably, covers its costs, but Roxane does not know prices charged by wholesalers. (Tab 65, 5-11-07 Waterer Dep. 577-80, 593-95; Tab 65, 5-9-07 Waterer Dep. 84-86) If Roxane negotiated a contract price with the provider purchasing the product from the wholesaler, then the provider pays the wholesaler this contract price plus any markup charged by the wholesaler. (Tab 65, 5-11-07 Waterer Dep. 577-80; Tab 65, 5-9-07 Waterer Dep. 84-86) Because the price paid by the provider is less than the price at which the wholesaler purchased the product from Roxane, Roxane pays the wholesaler a "chargeback" to make the wholesaler whole. (Tab 65, 5-11-07 Waterer Dep. 577-80, 593-95; Tab 65, 5-9-07 Waterer Dep. 84-86)

United States' Response: The United States disputes the statement that "Roxane does not know prices charged by wholesalers." In the minority of situations where Roxane did not have a pre-negotiated contract price with an indirect customer, Roxane was aware that the markup applied by the wholesaler was at most a few percentage points above the wholesaler's net acquisition cost. (Fauci Exhibit 11 (12/4/2008 Robert Sykora Dep.), at 208:7 - 210:5) Roxane knew or should have known that, in the case of indirect contract sales (where Roxane did have a pre-negotiated contract with provider customers), wholesalers honor the indirect contract price and do not apply a markup. (Fauci Exhibit 8 (6/17/2008 Matthew Erick Dep.), at 245-248)

111. There is no set formula that Roxane uses to set its WACs; rather it sets its WACs on a case-by-case basis based on market conditions. (Tab 65, 05-09-07 Waterer Dep. 71-72; Tab 65, 05-11-2007 Waterer Dep. 627-30) If Roxane's product was the only generic in the market, it would typically set WAC at 20% less than AWP, similar to how branded products set WAC. (*Id.*) If the generic market Roxane entered was already competitive, Roxane would typically set WAC at a greater percentage off of WAC. (*Id.*)

United States' Response: The United States does not dispute that Roxane set WACs differently for different products. The paragraph is otherwise disputed, and is not supported by the cited authority. Further answering, the phrase "market conditions" is ambiguous.

XIII. ROXANE'S PRICE REPORTING PRACTICES

112. Roxane provided AWPs to pricing compendia such as First DataBank and Red Book for the multi-source generic drugs at issue. (Tab 65, 5-9-07 Waterer Dep. 68; Tab 63, 4-1-03 Waterer Dep. 502) Roxane stopped reporting AWP for its branded products when it divested those products in 2001. *See* Section IX [Divestment], *supra*.

United States' Response: Undisputed. Further answering, the United States refers to its Local Rule 56.1 Statement of Undisputed Material Facts as to The Roxane Defendants (US-BR-SF), ¶¶ 18-21.

113. Up until late 1997 or early 1998, Roxane also supplied WAC prices to the pricing compendia for the all drugs at issue. (*Id.*) However, Roxane stopped providing WACs for its

multi-source generic products to the pricing compendia — including the (furosemide, azathioprine, diclofenac sodium, hydromorphone, and ipratropium bromide NDCs that are at issue in this case) — in late 1997/early 1998. (*Id.*) Instead Roxane opted to supply WAC prices directly to its customers and to state and federal government agencies upon request. (Tab 65, 5-11-07 Waterer Dep. 666-69) Roxane continued to provide WAC for its branded and branded generic products, including for the Roxanol, Roxicodone and Oramorph SR NDCs at issue in this case, after 1998 and until 2001 when it divested the products. (Tab 9, 7-25-07 Ciarelli Dep. 49-52)

United States' Response: The United States does not dispute that until approximately December 1997 Roxane reported WACs to the pricing compendia for the Subject Drugs. In or around December 1997, Roxane decided to stop reporting WACs for many multi-source products (including the furosemide, azathioprine, diclofenac sodium, hydromorphone, and ipratropium bromide NDCs at issue in this litigation). (Fauci Exhibit 48) When Roxane decided to stop reporting WACs for these products, plans were already in place to reduce the WACs for over 200 multi-source products in March 1998. (US-BR-SF, ¶¶ 124-25) Roxane knew that if it did not report its new (reduced) WACs, First Data Bank would continue to report Roxane's last published (and higher) WACs. (*Id.*)

The 1998 WAC changes were effective March 16, 1998, and Roxane notified customers by letter on Mach 13. (*Id.,* ¶ 126) Similar letters were *not* sent to state Medicaid programs, even though Roxane did not report its new WACs to First Data Bank. (Fauci Exhibit 12 (11/17/2004 Richard Feldman Dep.), at 125:17 - 126:22) The cited evidence does not support a finding that Roxane reported its WACs directly to any state governments or to the federal government. The United States further notes that in or around late 1999, Roxane instructed First Data Bank to remove its WACs from First Data Bank for several products. (US-BR-SF, ¶¶ 132-36)

The United States does not dispute that Roxane continued to publish WACs for its "branded generic" products after 1998 and until at least 2001.

114. Roxane stopped reporting WAC for its multisource products in late 1997 or early 1998 because it was not industry custom in the generic market to report WAC. (Tab 42, 7-26-07 Paoletti Dep. 179-82) Roxane did not want to publicly publish WAC because it was and is an actual transaction price for its drugs. (*Id.*; Tab 63, 4-1-03 Waterer Dep. 471-72)

United States' Response: Disputed. Roxane has offered no evidence to establish that it was "not industry custom in the generic market to report WAC." On the contrary, a corporate representative of First Data Bank testified that WACs are generally published "by manufacturers across the spectrum of the industry." (Fauci Exhibit 144 (11/13/2002 Patricia Kay Morgan Dep.), at 332:8 - 331:1) Roxane's stated reason for not publishing WACs is that Roxane purportedly regards WACs as confidential. Senior employees in Roxane's marketing department have testified that Roxane's WAC for a given drug is generally the same to all or most wholesalers, and that Roxane's WACs do not reveal the specific discounts or rebates given to a particular customer. (Fauci Exhibit 20 (10/24/2001 Judith Waterer Dep.), at 189:11 - 191:1, 193:14 - 193:23) When Thomas Russillo, Roxane's Director of multi-source marketing for several years during the relevant time frame, was asked if he considered a WAC to be confidential, he testified "I don't think it means much." (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 247:14 - 147:18)

115. Starting in 2004, Roxane began reporting an Average Sales Price ("ASP") to CMS pursuant to the Medicare Modernization Act of 2003. (Tab 138, 42 U.S.C. § 1396r-8(b)(3))

United States' Response: The United States does not dispute that starting in 2004, Roxane began to report ASPs to CMS for certain drugs, as required by the Medicare Modernization Act of 2003.

XIV. FULs FOR ROXANE'S DRUGS AT ISSUE

116. In 1987, the federal government adopted the Federal Upper Limit ("FUL") program to allow States to benefit from steep discounts in the generic market by encouraging migration to

lower-cost generic drugs. (42 C.F.R. §§ 447.331, 447.332 *et seq.*)

United States' Response: The United States does not dispute that in 1987, the United States Department of Health and Human Services promulgated regulations to establish aggregate upper limits of payment by Medicaid plans for multiple source and other drugs. The United States disputes Roxane's characterization of legislative history and rulemaking. Those regulations and the agency's description of the process for adopting them are contained in 52 Fed. Reg. 28,648 *et seq*. The stated purpose of the regulations was to address concerns with the HHS' then-current reimbursement system and "to take advantage of savings that are currently available in the marketplace for multiple source drugs . . ." (*Id.*) The statements in this paragraph are otherwise denied and are not supported by the cited authority.

117. The FUL program was intended to "enable[] the Federal and State governments to take advantage of savings that are … available in the marketplace for multiple source drugs" while at the same time maintaining flexibility for States to determine their own reimbursement rates and to experiment with methods of further controlling the cost of offering Medicaid beneficiaries a prescription drug benefit. (Tab 83, 52 Fed. Reg. 28648 (July 31, 1987)) The FUL regulation provides that a State's reimbursement for multiple source drugs "in the aggregate" must not exceed 150% of the lowest published price for the least costly therapeutically equivalent product where at least three suppliers market a given generic drug. (42 C.F.R. § 447.332) CMS generally looks to ensure that there are at least two A-rated drugs in the FDA's Orange Book, or, if there is a B-rated drug, three A-rated drugs when establishing a FUL. (Tab 26, 1-24-08 Gaston Dep. 56)

United States' Response: The United States does not dispute that the FUL program was adopted to enable "the Federal and State governments to take advantage of the savings that are currently available in the marketplace for multiple source drugs" and to maintain "State flexibility in the administration of the Medicaid program." 52 Fed. Reg. at 28,648. The United States admits that under the "aggregate limits" of the FUL program, State agencies are free to experiment with alternative payment systems[.]" (*Id.*) The statements in the first sentence of this

paragraph are otherwise denied and are not supported by the cited authority.

The United States does not dispute the second sentence of this paragraph. Pursuant to 42 C.F.R. § 447.332(a)(1)(ii), CMS utilized prices listed in "published compendia" (i.e., AWPs, WACs and Direct Prices) in setting FULs. (Fauci Exhibit 145 (Declaration of Sue Gaston (hereinafter, "Gaston Decl.")), ¶ 6) Persons responsible for setting FULs at CMS did not use AMPs, as AMPs are not prices listed in "published compendia." (*Id.*, ¶ 6; Fauci Exhibit 146 (3/19/2008 Sue Gaston Dep.), at 528:4 - 529:1; United States' Local Rule 56.1 Statement of Undispputed Material Facts Common to All Defendants (US-C-SF), ¶ 12) The phrase "generally looks to" as used in the third sentence of this paragraph is ambiguous and is not supported by the cited authority. CMS may only set FULs for multiple source drugs that meet certain statutory criteria and regulatory requirements, including that there be at least three therapeutic and pharmaceutical equivalents, as reflected in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book"). 42 U.S.C. § 1396r-8(e)(4) In addition, there must be at least three suppliers for a FUL drug, as reflected in all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally." 42 C.F.R. § 447.332(a)(1)(ii)

118. To establish FULs, HCFA relied on an automated system that used drug and pricing data to compile an initial list of drugs and FULs. (*Id*. 232-34) Then HCFA engaged in a "manual review" of the initial list whereby HCFA employees would often adjust FULs in order to "make sure that the FUL price that's set is a reasonable price and that we'll be assured the availability of the drug." (Tab 27, 3-19-08 Gaston Dep. 442-45) HCFA set FULs that it believed could both achieve cost-savings and provide sufficient access to care such that providers could actually acquire drugs at the FUL price. (*Id.* 428-29, 498-99) HCFA acknowledged that it was "building into [FUL] rates for ingredients a profit margin for pharmacists." (Tab 83 Abbott Ex. 284, 52 Fed. Reg. 147, 28656 (July 31, 1987)) In some cases, CMS will decline to set a FUL for that specific drug if drugs are not likely to be available at the FUL price or there will not be a cost savings to states by establishing a FUL. (Tab 27, 3-19-08Gaston Dep. 451)

United States' Response: CMS utilized a program known as the Federal Upper Limit System ("FUL System") in setting FULs, and that the FUL System downloaded information from the Orange Book as well as information from pricing compendia to create listings of published prices for drugs statutorily eligible for a FUL. (Fauci Exhibit 147 (1/24/2008 Sue Gaston Dep.), at 232:18 - 234:18) The United States admits that CMS employees then reviewed the price listings generated by the FUL System to ensure, among other things, that the drug would be available at the FUL price and that the FUL would generate cost savings to the federal government because it would be lower than the reported AWPs. (Fauci Exhibit 146 (3/19/2008 Sue Gaston Dep.), at 456:6 - 457:6) If the lowest published price appeared to be significantly lower than the next available published price, CMS employees contacted manufacturers to determine if the published price was valid and nationally available. In addition, CMS employees generally would not use the lowest published price if it resulted in a FUL that was not higher than at least three other published prices. (Fauci Exhibit 145 (Gaston Decl."), ¶¶ 4-5)

The United States disputes that "HCFA acknowledged that it was 'building into [FUL] rates for ingredients a profit margin for pharmacists.'" Instead, CMS acknowledged that because the federal upper limit standards were aggregate in nature, state Medicaid programs had "the ability to make payment at levels above the specific standard for certain drugs, provided that the agency makes the payment at levels below the specific standard for other drugs." 52 Fed. Reg. 28,648. The paragraph is otherwise denied, and is not supported by the cited authority.

119. The FUL regulation did not establish a reimbursement rate for any drug, but afforded States flexibility in setting reimbursement rates for particular drugs so long as the state reimburses at or below the applicable FUL limitation. (42 C.F.R. §§ 447.304, 447.331-334)

United States' Response: Undisputed. Further answering, the United States notes that the

FULs set for specific drugs were incorporated into all or nearly all state Medicaid programs' reimbursement formulas as a component of a "lower of" reimbursement methodology. (US-C-SF-¶¶ 21-33)

120. The FULs set by CMS for Roxane's subject drugs are as follows:

Drug Name	NDC	FUL	Begin Date	End Date
Furosemide 10mg/ml solution 60s	00054-3294-46	$.01142	July 1, 1997	March 31, 2000
		$.1300	April 1, 2000	Present
Furosemide 10mg/ml solution 120s	00054-3294-50	$.1249	July 1, 1997	July 1, 1998
		$.0893	April 1, 2000	November 19, 2001
Furosemide 20mg tablet, 100s	00054-4297-25	$.0158	July 1, 1990	September 30, 1992
		$.0189	October 1, 1992	April 30, 1994
		$.0203 from May 1, 1994	October 31, 1996	October 31, 1996
		$.021	November 1, 1996	March 31, 2000
		$.042	April 1, 2000	November 19, 2001
		$.0453	November 20, 2001	March 4, 2002
		$0.563	March 5, 2002	Present
Furosemide 40 mg tablet, 100s	00054-4299-25	$.0173	July 1, 1990	September 30, 1992
		$.0222	October 1, 1992	September 30, 1993
		$.0251	October 1, 1993	September 30, 1994
		$.027	October 1, 1994	May 30, 1996
		$.0248	June 1, 1996	October 31, 1996
		$.0254	November 1, 1996	March 31, 2000
		$.044	April 1, 2000	November 19, 2001
		$.0522	November 20, 2001	March 4, 2002
		$.0599	March 5, 2002	Present
Furosemide 80 mg tablet, 100s	00054-4301-25	$.045	July 1, 1990	September 30, 1992
		$.053	October 1, 1993	April 30, 1994

Drug Name	NDC	FUL	Begin Date	End Date
		$.0531	May 1, 1994	September 30, 1994
		$.0563	October 1, 1994	June 30, 1997
		$.0473	July 1, 1997	March 31, 2000
		$.071	April 1, 2000	November 19, 2001
		$.0915	November 20, 2001	March 10, 2003
		$.1043	March 11, 2003	Present
Diclofenac Sodium 50 mg tablet, 100s	00054-4221-25	$.8375	June 1, 1996	October 31, 1996
		$.8544	November 1, 1996	June 30, 1997
		$.8285	July 1, 1997	July 1, 1998
		$.749	July 2, 1998	March 31, 2000
		$.4748	April 1, 2000	Present
Diclofenac Sodium 75 mg tablet, 100s	00054-4222-25	$1.014	June 1, 1996	October 31, 1996
		$.9647	November 1, 1996	June 30, 1997
		$.9219	July 1, 1997	March 31, 2000
		$.656	April 1, 2000	November 19, 2001
		$.585	November 20, 2001	Present
Ipratropium Bromide .02% Solution for Inhalation, 2.5ml, 25s	00054-8402-11	$.303	August 24, 2003	November 1, 2003
		$.234	November 2, 2003	February 13, 2005
		$.108	February 14, 2005	Present

(Tab 139, 11-21-08 United States' Objections and Supplemental Response to Interrogatory No. 7, served at 13-14)

United States' Response: Undisputed.

121. However, CMS did not always set FULs for certain drugs that were statutorily eligible for a FUL. (Tab 140, Abbott Ex. 108 at 6, OIG Feb. 2004, *Omission of Drugs from the Federal Upper Limit List in 2001*, (OEI-03-02-00670) (Feb. 2004 OIG Report)) ("Medicaid could have saved $123 million in 2001 by adding 55 drug products to the Federal Upper Limit list. This represents 30 percent of the $411 million Medicaid reimbursed for the 55 products that year. Each of these drug products had at least three versions rated therapeutically equivalent by FDA and were available from three or more suppliers.")

United States' Response: The United States does not dispute that CMS did not set FULS for each and every drug that met the statutory criteria. CMS policy was generally to attempt to set FULs for eligible drugs that were the most commonly used and dispensed by pharmacies. (Fauci Exhibit 146 (3/19/2008 Sue Gaston Dep.), at 322:20 - 323:6; Fauci Exhibit 147 (1/24/2008 Sue Gaston Dep.), at. 250:7 - 250:22) Further answering, the United States notes that by 2004, the FUL list included over 400 drug products. (Tab 140, at ii)

122. The OIG specifically noted that ipratropium bromide, a drug at issue in this Action, was one of "(f)our drug products [(that)] accounted for 71 percent of the $123 million in potential Medicaid savings in 2001." (*Id.*) Had CMS followed its own guidelines and implemented a FUL for ipratropium bromide, the Medicaid program would have saved nearly $20 million in 2001 alone. (*Id.* at 7) CMS failed to implement a FUL for ipratropium bromide until August 24, 2003. (*Id.*)

United States' Response: The United States does not dispute that the OIG noted that ipratropium bromide was one of "[f]our drug products [that] accounted for 71 percent of the $123 million in potential Medicaid savings in 2001." Further answering, by the time the OIG published the referenced study in February 2004, CMS already had instituted a FUL for ipratropium bromide in August 2003. (Tab 140, at 7)

123. The OIG also studied Medicare reimbursement for ipratropium bromide and found that had CMS reimbursed Medicare providers based on the FUL implemented in 2003 instead of the pre-2004 Medicare reimbursement guideline of 95% of AWP, the Medicare program and its beneficiaries would have saved $386 million in 2002 alone. (Tab 141, Abbott Ex. 122 at ii-iv, OIG, Jan 2004, *Update: Excessive Medicare Reimbursement for Ipratropium Bromide*, (OEI-03-03-00520) (Jan. 2004 OIG Report)) ("This report is part of a series of reports on ipratropium bromide that have consistently found that the published average wholesale prices, which, as prescribed by Federal law, form the basis of Medicare drug reimbursement, bear little or no resemblance to actual wholesale prices that are available to pharmacies and large Government purchasers."))

United States' Response: The United States does not dispute that in January 2004 the OIG published the referenced study, or that the study found that in 2002 Medicare reimbursement for

ipratropium bromide was higher than it would have been had Medicare reimbursed for ipratropium bromide at the level of the FUL set by CMS in August 2003.

XV. ROXANE PROVIDED AMPs DIRECTLY TO CMS

124. Congress created the Medicaid Drug Rebate Program ("Rebate Program") in the Omnibus Budget Reconciliation Act of 1990. Under the Rebate Program, for Roxane's drugs to be eligible for reimbursement under Medicaid, the manufacturer is required to enter into a national Medicaid Rebate Agreement with the Centers for Medicare and Medicaid Services ("CMS"). (42 U.S.C. § 1396r-8(a)(l); 56 Fed. Reg. 7049 (Feb. 21, 1991)).

United States' Response: Undisputed. Further answering, once a manufacturer enters a rebate agreement with CMS, state Medicaid programs are required, with certain limited exceptions, to reimburse providers for that manufacturer's drugs. 42 U.S.C. § 1396r-8(d)

125. Pursuant to the Medicaid Rebate Agreement Roxane signed with CMS, Roxane calculated the Average Manufacturer Price ("AMP") for all of its products – including all of the drugs at issue in this case – during the entire time period relevant to this case, and reported that number to CMS on a quarterly or monthly basis. (Tab 14, 5-30-07 DeCapua Dep. 115-16; Tab 15, 7-15-08 DeCapua Dep. 16, 57-59; Tab 142, Scott Ex. 28, Sept. 2001 Medicaid Drug Rebate Operational Training Guide; Tab 143, 1991 Rebate Agreement entered into by Roxane Laboratories, Inc., dated 2-27-91 ("Roxane Rebate Agreement"))

United States' Response: Undisputed. Pursuant to the Rebate Program, the AMPs provided to CMS are confidential and not to be disclosed by CMS except for the purpose of carrying out the Rebate Program. 42 U.S.C. § 1396r-8(b)(3)(D) The Rebate Agreement entered into between Roxane and CMS specifically notes that "information disclosed by the Manufacturer in connection with this Agreement is confidential and, notwithstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency . . ." except as necessary to further the purposes of the Rebate Agreement. (Tab 143, at 9) Responsible officials at CMS testified that they understood AMPs were confidential, and could only be used for purposes of the Rebate Program. (US-C-SF, ¶¶ 11-14)

126. Roxane calculated AMP according to CMS guidelines. (Tab 14, 5-30-07 DeCapua Dep. at 29, 137-42; Tab 15, 7-15-08 DeCapua Dep. at 61-65) Specifically, AMP is defined by statute as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." (42 U.S.C. § 1396r-8(k)(1)) AMPs "include cash discounts, free goods, volume discounts, and rebates." (Tab 144, H.R. No. 101-881, reprinted in 1990 U.S.C.C.A.N. 2017, 2060 [*quote from 2109] (1990); *see also* Tab 14, DeCapua 5-30-07 Ex. 82 at 2, "Boehringer Ingelheim Medicaid Reporting Requirements") AMP is therefore an average price, including discounts, to the retail class of trade under a defined set of circumstances. (Tab 15, 7-15-08 DeCapua Dep. at 39-40, 61-65, 78)

United States' Response: The United States does dispute that AMP is defined by statute, and that the definition is set forth at 42 U.S.C. § 1396r-8(k)(1). The United States lacks sufficient information to admit or deny the first sentence of this paragraph. The paragraph is otherwise disputed, and is not supported by the cited authority.

127. The AMP prices reported by Roxane to CMS throughout the relevant time period generally tracked the "Derived AWPs" calculated by Plaintiffs' expert, Dr. Mark. The below graph illustrates this relationship for ipratropium bromide, and the results are similar for the other Roxane drugs at issue. (Tab 188, D. Williams Aff. at ¶ 15)

[Graph included in Roxane's SOF is not reproduced here]

United States' Response: Disputed. The statement that the AMPs reported by Roxane to CMS pursuant to the Rebate Program "generally tracked the 'Derived AWPs' calculated by Plaintiffs' expert, Dr. Mark Duggan" is ambiguous, and is not supported by the cited authority.

128. CMS was not the only federal agency with access to Roxane's AMP information. The Department of Health & Human Services Office of Inspector General ("OIG") also had access to AMPs reported by drug manufacturers. (Tab 57, 2-6-08 Vito Dep. 1096-99, 1194-98) (Tab 52, 12-13-07 Tawes Dep. 879-80) In fact, the OIG was given direct access to Roxane's reported AMPs and could view such information without first requesting it through CMS. (Tab 57, 2-6-08 Vito Dep. 1197-98)

United States' Response: The United States notes that the OIG is part of the United States Department of Health and Human Services. The United States does not dispute that the OIG was provided access to Roxane and other manufacturers' AMPs. Responsible officials at OIG

testified that they understood AMPs were confidential, (*see* US-C-SF, ¶ 11-14), and OIG and other governmental reports regularly referred to AMPs as confidential. (*See*, *e.g.* Tab 91, at 20, Box 2 ("the average manufacturer price (AMP), used to calculate the Medicaid rebate, is not public information"); Tab 147, at i ("Most State Medicaid agencies do not have access to AMP data, which is proprietary"); Tab 146, at 3 ("Section 1927(b)(3)(D) of the Social Security Act requires that, subject to certain exceptions, AMPs reported to CMS not be publicly disclosed"))

129. Several Federal agencies, including the OIG and Congressional Budget Office ("CBO"), used AMPs reported by manufacturers extensively in reports comparing AMP prices to AWPs, FULs, and other published prices. *See, e.g.*, Tab 91, Dey Ex. 173A at 20, Box 2, Jan. 1996 CBO Report, "How The Medicaid Rebate On Prescription Drugs Affects Pricing In The Pharmaceutical Industry," (1996 CBO Report)); Tab 146, Dey Ex. 009, OIG June 2005, OIG, Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices, OEI-03-05-00110, (June 2005 OIG Report)); Tab 147, Littlejohn Ex. 233, OIG June 2005, Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices, OEI-05-05-00240, June 2005; Tab 148, OIG April 2006, Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices, OEI-03-04-00430 (April 2006 OIG Report.)

United States' Response: The United States does not dispute the OIG and the CBO compared AMPs to AWPs in the referenced reports. The paragraph is otherwise disputed, and is not supported by the cited authority. Further answering, the report cited at Tab 91 (1996 CBO Report, "How The Medicaid Rebate On Prescription Drugs Affects Pricing In The Pharmaceutical Industry,") found that for the 224 products that were the top-selling Medicaid drugs in 1993, "the AMP averaged 80 percent of the AWP." (Tab 91, at 20, Box 2; *see supra* United States' Response to Paragraph 128)

XVI. STATES ALSO GAIN INFORMATION FROM ROXANE'S AMPs

130. CMS used Roxane's AMP information to calculate and send to the states a "Unit Rebate Amount" (URA) for each covered drug. The states then used the URA to calculate federally-mandated rebates Roxane was required to pay by multiplying the URA by the number of units of the drug supplied to Medicaid beneficiaries. (42 U.S.C. § 1396r-8(b)(3)(A); Tab 14, 5-

30-07 DeCapua Dep. 50; Tab 15, 7-15-08 DeCapua Dep. 57-59) For most generic drugs, the URA is equal to 11% of the product's AMP provided to CMS by Roxane. (42 U.S.C. § 1396r-8(c)(3); Tab 44, 10-2-08 L. Reed Dep. 1315-16; Tab 14, 5-30-07 DeCapua Dep. 161-62)

United States' Response: The term "[f]or most generic products" is ambiguous as it is used in the third sentence of this paragraph. The United states does not dispute that CMS used Roxane's AMPs to calculate and send to state Medicaid programs URAs which states then used for the sole purpose of determining rebates under the Rebate Program. The rebate for drugs other than single source and innovator multiple source drugs was 11% of AMP.

131. Because the formula for calculating the URA for most generic drugs is very simple — 11% of a drug's reported AMP — states could easily determine a drug's AMP from the URA provided to the State by CMS. (Tab 39, 7-11-07 Megathlin (Massachusetts) Dep. 139-41; Tab 28, 1-15-09 Gladden (Texas) Dep. 55-57) Indeed several States admitted to reverse calculating AMP from the URAs received from CMS. (Tab 31, 6-14-07 Jeffrey (Massachusetts) Dep. 114-15; Tab 28, 1-15-09 Gladden (Texas) Dep. 98-100).

United States' Response: The United States does not dispute that the formula for calculating URAs is set forth in 42 U.S.C. § 1396r-8(c)(1) and (3). The paragraph is otherwise denied, and is not supported by the cited authority. Further answering, the Massachusetts Medicaid program did not "reverse calculate" AMPs from the URAs received from CMS. (Fauci Exhibit 148 (10/3/2007 Arnold Shapiro Dep.), at 170:13 - 170:19, 173:7 - 173:13; Fauci Exhibit 149 (6/14/2007 Paul Jeffrey Dep.), at 220:8 - 221:11; Fauci Exhibit 150 (7/26/2007 Gary Gilmore Dep.), at. 144:1 - 145:20) Further answering, state Medicaid programs understood AWPs were confidential and did not attempt to calculate AMPs based on URAs, or to otherwise use AMPs in setting reimbursement rates. (US-C-SF, ¶ 115)

132. State Medicaid programs understood the significance of AMPs and wanted AMP information so they could compare AMPs to prices used for reimbursement. (Tab 28, Gladden (Texas) Ex. 38 at 3 (State Medicaid Directors' Association Pharmacy Reform TAG meeting minutes reflecting discussion regarding the States' "need to know both AMP and best price for policy reasons (to establish a pharmacist reimbursement baseline)…"); Tab 28, 1-15-09

Gladden(Texas) Dep. 47-48, 96-97; Tab 150, KS 00000042 (Kansas Medicaid compared AMPs provided by CMS to FULs and MACs used for drug reimbursement))

United States' Response: Disputed. The phrase "understood the significance of AMPs" is ambiguous. The United States does not dispute that officials at some state Medicaid programs, including Patricia Gladden of the Texas Vendor Drug Program, testified that AMPs would assist state Medicaid programs in determining pharmacists acquisition costs, and that such information would be useful due to widespread reporting of inflated AWPs. (Tab 28, p. 47-48) However, state Medicaid programs understood that the federal government treated AMPs as confidential. (*Id.*; *see also* US-C-SF, ¶¶ 115**)**

133. Though only restriction of the states' use of URA information is that states cannot publicly disclose the identity of a specific manufacturer or prices charged by that manufacturer. Under federal regulations State Medicaid programs were permitted to use URA and AMP information as a "baseline" for reimbursement and as a comparison for reimbursement benchmarks. (Tab 138, 42 U.S.C. § 1396r-8(b)(3)(D) ("(I)information disclosed by manufacturers or wholesalers … is confidential and shall not be disclosed by … a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler (or) prices charged for drugs by such manufacturer or wholesaler …."); Tab 143, Roxane Rebate Agreement § VII; Tab 28, 1-15-09 Gladden Dep. 60-61, 92-93; 96-97)

United States' Response: The first sentence of this paragraph is ambiguous and does not make sense as written. The paragraph is otherwise disputed. The Rebate Statute, as well as the Rebate Agreement executed between Roxane and CMS, require that AMPs be used only for purposes of the Rebate Program. (*See supra* United States' Response to Paragraphs 130-132; US-C-SF, ¶¶ 111)

134. Indeed, some States have passed laws requiring manufacturers to provide AMPs directly to State Medicaid programs, including Texas (2002), Vermont (2008), New Mexico (2005), and Maine (2005). (*Id*. 94-96; VT. STAT. ANN. tit. 33, § 2010 (Vermont); N.M. STAT. § 27-2E-1 (New Mexico); ME. REV. STAT. ANN. tit. 22, § 2698-B (Maine))

United States' Response: Undisputed. Further answering, when Roxane has provided AMPs

directly to state Medicaid programs it describes the AMPs as "extremely sensitive and proprietary" and cautions that the AMPs "should not be disseminated by your department to any outside persons or entities." (Fauci Exhibit 151)

XVII. THE GOVERNMENT'S NOVAPLUS CLAIMS

A. Roxane Named And Priced NovaPlus Label Ipratropium Bromide Identically To Roxane Label Ipratropium Bromide And Considered Both Generic Drugs.

135. In June 1996, Roxane began manufacturing and marketing the first generic version of the chemical compound, ipratropium bromide, which is used to treat symptoms associated with chronic respiratory conditions. (Tab 62, 10-24-01 Waterer Dep. 38-39; Tab 65, 5-10-07 Waterer Dep. 292-94.) Roxane marketed and sold the drug under the name "Ipratropium Bromide Inhalation Solution 0.02%." (Tab 151, RLI-AWP 00212508-09 at RLI-AWP 00212508 (9-19-2000 Ltr. from J. Powers to S. Norvell).)

United States' Response: Undisputed.

136. Both prior to 1996 and thereafter, the brand-name product for ipratropium bromide was sold and marketed under the proprietary trade name "Atrovent." (Tab 5, 12-12-08 C. Carr-Hall Dep. 244; Tab 152, Decl. C. King ¶ 18.)

United States' Response: The United States does not dispute that ipratropium bromide is the generic equivalent of Atrovent, and that Atrovent is a branded product sold and marketed under a proprietary name by Roxane's sister corporation (BIPI). Product announcements identified Atrovent as a proprietary trade name as follows: "Atrovent®." (*See, e.g.,* Fauci Exhibit 152) The paragraph is otherwise disputed, and is not supported by the cited authority.

137. In accordance with industry practice, Roxane set the AWP for its new ipratropium bromide generic product at approximately 10% below the AWP of Atrovent. (Tab 64, 11-28-05 Waterer Dep. 37; Tab 65, 5-9-07 Waterer Dep. 186-87; Tab 65, 5-11-07 Waterer Dep. 604.)

United States' Response: The United States does not dispute that Roxane set the AWP for its ipratropium bromide product at approximately 10% below the AWP of Atrovent. The United States disputes that this decision was made pursuant to any understanding of "industry practice."

(*See supra* United States' Response to Paragraph 99)

138. In 1997, Dey Laboratories launched a competing generic product, also named after the generic chemical compound, "Ipratropium (Bromide Inhalation Solution 0.02%.)" (Tab 36, 03-17-08 Lockwood Dep. 646-48; Tab 5, Carr-Hall Dep. Ex. 40 at BOEH01050028, "Dey Recognize the Difference" (Dey Marketing Flier).) This product had a Dey label. (*Id*.)

United States' Response: Undisputed.

139. From 2000 onward, numerous generic manufacturers entered the ipratropium bromide marketplace, including Alpharma, Zenith Goldline, and others. (Tab 185, Roxane Ex. 118 at AWP033-434–AWP033-435, AWP033-0372–AWP033-373 (AdminaStar Federal pricing arrays); Tab 53, 12-2-08 Tawes Dep. 978.) Like the Roxane and Dey products, all of these manufacturers named their generic products after the chemical compound name, "ipratropium bromide," and all carried the respective manufacturer or distributor label. (Tab 154, 2001 RedBook at 368.)

United States' Response: The United States does not dispute that other manufacturers entered the multi-source ipratropium bromide market following Dey Laboratories, and that such manufacturers marketed their products as "ipratropium bromide."

140. In 1998, Roxane and Dey bid on a private-label contract to sell generic ipratropium bromide through Novation LLC, a large group-purchasing organization (GPO) that targets the hospital class of trade. (Tab 155, RLI-AWP-00122465-470 at RLI-AWP 00122467, "Novation Agreement Launch Package, Confidential" (NovaPlus Ipratropium Agreement Launch Package); Tab 66, 12-12-08 C. Carr-Hall Dep. 236-237; Tab 5, 12-12-08 Waterer Dep. 116.)

United States' Response: Undisputed. Further answering, the United States notes that Novation, LLC was created in January 1998 as a purchasing agent representing several thousand health care organizations in the UHC and VHA hospital networks. (Fauci Exhibit 153) At the time of bidding, Roxane expected that Novation would be one of the two largest group purchasing organizations in the country within 12 months. (*Id.*)

141. In order to facilitate the sale of lower-priced products to its member hospitals, Novation created a private label program—the "Products Lowered Utilizing Standardization" or "NovaPlus" label—which consists of over 300 generic products, all of which carry the private-label designation of "NovaPlus" to identify the supplier for Novation's hospital members. (Tab 156, htttp://www.novationco.com/suppliers/novaplus.asp; Tab 157, http://www.novationco.

com/programs/enhanced_savings.asp.) As part of the NovaPlus program, Novation contracts with manufacturers of pharmaceuticals and medical equipment to supply products that will be sold exclusively to Novation GPO members at discounted prices under the "NovaPlus" label. (Tab 156, http://www.novationco.com/suppliers/novaplus.asp; Tab 157, http://www.novationco.com/programs/enhanced_savings.asp.)

United States' Response: The United States admits that Novation created a private label program known alternatively as "NovaPlus" or "NOVAPLUS." The United States does not dispute that "the NOVAPLUS product portfolio includes more than 300 product categories." (Tab 157) The paragraph is otherwise denied, and is not supported by the cited authority. Further answering, Novation owns the proprietary trade name of "NOVAPLUS" and Novation contracts with various pharmaceutical manufacturers to supply products to Novation members under the NOVAPLUS brand. (Fauci Exhibit 154) According to Novation, "the NOVAPLUS brand has helped smaller manufacturers - with less common market recognition - compete effectively with manufacturers many times their size." (Fauci Exhibit 155, at RLI-AWP-00127475; *see also* Tab 156 ("NOVAPLUS. . .is a low cost brand of pharmaceutical.")) Novation also claims that NOVAPLUS "delivers value to suppliers through," among other things, "solid brand recognition." (Fauci Exhibit 155, at RLI-AWP-00127475) Other Novation documents expressly state that Novation owns the "NOVAPLUS" trademark, and that suppliers participating in the NovaPlus program must "legibly apply the appropriate Mark or Marks to each item and all cartons and cases of and for each and every one of the Private Label Products." (Fauci Exhibit 154, at BOEH04393947)

According to a National Accounts Monthly Report from August 1998, Novation represented $12 million in ipratropium bromide business, of which Roxane held 60%. Roxane expected that "whoever is placed in the Plus program will be at 80% share within 90 days."

(Fauci Exhibit 156, at BOEH00138418) In a National Accounts Monthly Report dated December 1998, Tom Via (then a Roxane National Account Manager) stated that he could not "stress strongly enough how beneficial this program will be to the BI companies on the whole and specifically to [Roxane]." (Fauci Exhibit 157, at BOEH01046836)

142. In early 1999, Roxane was awarded the NovaPlus contract by Novation and began to manufacture generic ipratropium bromide for sale exclusively to Novation's hospital members under the NovaPlus label. (*Id*.; Tab 158, RLI-AWP-00122479–RLI-AWP-00122482 at RLI-AWP-00122479 (Novation, LLC Agreement Announcement).) Like Roxane's and Dey's products, the Novation product was named after the generic chemical name, "Ipratropium Bromide Inhalation Solution 0.02%," but carried the "NovaPlus" label, rather than a Roxane label. (Tab 151, RLI-AWP 00212508-09 (9-19-2000 Ltr. from J. Powers to S. Norvell); Tab 155, NovaPlus Ipratropium Agreement Launch Package at RLI-AWP 00122468; Tab 159, RLI-AWP-00008196 (April ' 99 New from Roxane).)

United States' Response: Disputed. Roxane offers no evidence to support a finding that its NovaPlus ipratropium bromide products were "named after the generic chemical name." On the contrary, the evidence shows that the products were marketed under the proprietary and trademarked name of "NOVAPLUS." Roxane launched its NovaPlus ipratropium bromide products in or around June 1999. Announcements sent by Roxane identified the product as follows: "Ipratropium Bromide Inhalation Solution 0.02% (NovaPlus®)." (Fauci Exhibit 158; *see also* Tab 161 ("Roxane Laboratories anticipates having NOVAPLUS™ product to ship. . .")) In a May 1999 letter to wholesalers, Roxane announced "an agreement with Novation LLC, to begin distributing and promoting Ipratropium Bromide Inhalation Solution 0.02% with a NOVAPLUS® label." (Tab 158) Handwritten comments to a draft version of the May 1999 letter noted that the product should be described as "NOVAPLUS®." (Fauci Exhibit 159)

Roxane launched its NovaPlus ipratropium bromide products under different NDCs than its "Roxane label" ipratropium bromide. Specifically, the NovaPlus ipratropium bromide

products had NDCs 00054-8404-11, 00054-8404-13 and 00054-8404-21 (the "NovaPlus ipratropium bromide products" or the "8404 products"). The Roxane label ipratropium bromide products had NDCs 00054-8402-11, 00054-8402-13 and 00054-8402-21 (the "Roxane-label ipratropium bromide products" or the "8402 products.")

143. Shortly before the product's launch in June 1999, Roxane sent out letters announcing the private-label agreement. (*See, e.g*, Tab 158, Novation Agreement Announcement, RLI-AWP-00122479-82.) These letters identified the new product as"Ipratropium Bromide Inhalation Solution 0.02% with a NOVAPLUS® label" and "Ipratropium Bromide Inhalation Solution 0.02% (NovaPlus)." (Tab 158, Novation Agreement Announcement at RLI-AWP-00122479-82; Tab 159, April '99 New from Roxane at RLI-AWP 00008196).

United States' Response: Undisputed. (*See supra* United States' Response to paragraph 142)

144. Roxane's letters also listed new Roxane NDCs for the product and the same AWPs for the NovaPlus labeled products that were used for Roxane's other generic ipratoprium bromide products. (Tab 158, Novation LLC Agreement Announcement at RLI-AWP- 00122479-82; Tab 159, April '99 New from Roxane at RLI-AWP 00008196).

United States' Response: The United States does not dispute that Roxane's NovaPlus ipratropium bromide products had different NDCs than Roxane's other ipratropium bromide products. (*See supra* United States' Response to Paragraph 142) The United States also does not dispute that Roxane's NovaPlus ipratropium bromide had the same AWPs as the Roxane-label ipratropium bromide. Further answering, the United States notes that letters sent by Roxane announcing price reductions distinguished between NovaPlus ipratropium bromide products (i.e., the 8404 products) and the "Roxane-label" ipratropium bromide products (i.e., the 8402 products). For example, a September 19, 2000 letter separately listed reduced prices for "Ipratropium Bromide Inhalation Solution - NOVAPLUS, 0.02%" and "Ipratropium Bromide Inhalation Solution, 0.02%." (Fauci Exhibit 160) Internal Roxane documents distinguish between the "Roxane-label" ipratropium bromide product and the "NovaPlus" or "Plus" label

ipratropium bromide. (*See*, *e.g.,* Fauci Exhibit 161; Fauci Exhibit 162)

145. The AWPs for the Roxane and NovaPlus label ipratroprium bromide products were identical. The following chart shows the AWPs for each of these products, which remained the same throughout the pertinent time period

Package Size	Roxane ipratroprium bromide	NovaPlus ipratropium bromide
25	$44.06	$44.06
30	$52.87	$52.87
60	$105.74	$105.74

(Tab 158, Novation LLC Agreement Announcement at RLI-AWP-00122479-82.)

United States' Response: Undisputed.

146. Roxane sold the NovaPlus label ipratropium bromide to Novation members at a contract price that was at or at times lower than the contract price for Roxane label ipratropium bromide. (Tab 151, 9-19-2000 Ltr. from J. Powers to S. Norvell at RLI-AWP 00212508).)

United States' Response: Undisputed.

147. It was Roxane's understanding that NovaPlus was a generic pharmaceutical product. (Tab 66, 12-12-08 Waterer Dep. 105)

United States' Response: Disputed. Further answering, the term "generic pharmaceutical product" is ambiguous as used in this paragraph. Roxane understood that it was marketing the NovaPlus ipratropium bromide products under the NOVAPLUS label, and Roxane understood that NOVAPLUS was a proprietary trademark name. (*See supra* United States' Responses to Paragraphs 141-42, 144)

148. Novation also sent mailings to its members announcing it would "introduce Iptratropium Bromide into the NOVAPLUS™ line of products." (Tab 160, 4-6-99 S. Norvell Memo to Novation Authorized Distributors at RLI-AWP 00224752; Tab 161, 4-14-1999 S. Norvell Revised Memo to Novation Authorized Distributors at RLI-AWP 00122471-85.) Another mailing announced the launch of "NOVAPLUS™ Ipratropium Bromide." (Tab 155, NovaPlus Ipratropium Bromide Agreement Launch Package at RLI-AWP 00122465-70.)

United States' Response: Undisputed. (*See supra* United States' Responses to Paragraph 141-42, 144)

149. From June 1999 until May 2004, the NovaPlus label ipratropium bromide was sold exclusively to Novation members under the private-label agreement. (Tab 155, NovaPlus Ipratropium Bromide Agreement Launch Package at RLI-AWP 00122465-70; Tab 162, BOEH01522558, "The Multi-Source Gold Sheet, March 22, 2004" (March Gold Sheet); Tab 163, BOEH02953413, "The Multi-Source Gold Sheet, April 8, 2004" (April Gold Sheet); Tab 164, BOEH02953409, "The Multi-Source Gold Sheet, May 3, 2004" (May Gold Sheet).)

United States' Response: Undisputed.

150. Roxane and Novation's Agreement was initially set to expire in January 2004. (Tab 155, NovaPlus Ipratropium Bromide Agreement Launch Package, RLI-AWP 00122465-70). But due to lack of demand, the decision to discontinue NovaPlus ipratropium bromide was made in June 2003 and official notice was sent to Novation in July 2003. (Tab 165, BOEH04310697, 7-11-03 Ltr. from L. Paoletti to R. Day). The NovaPlus-label ipratropium bromide product was discontinued between March-May 2004. (Tab 162, March Gold Sheet at BOEH01522558; Tab 163, April Gold Sheet at BOEH02953413; Tab 164, May Gold Sheet at BOEH02953409.)

United States' Response: The United States does not dispute that Roxane discontinued its NovaPlus ipratropium bromide products in or around June 2003. The paragraph is otherwise disputed, and is not supported by the cited authority.

B. The Medicare Regulatory Framework For Hospital Reimbursements Under The Medicare Parts A and B.

151. Drugs dispensed to Medicare beneficiaries during inpatient hospital stays are not paid for separately but are reimbursed along with procedures as part of a bundled package through diagnosis-related groups under Medicare Part A. *See* 42 U.S.C. § 1395ww(a)(4).

United States' Response: Undisputed.

152. Beginning on July 1, 2000, drugs dispensed to Medicare beneficiaries during outpatient hospital visits to Hospital Outpatient Departments (OPDs), including hospital pharmacies, are reimbursed under Medicare Part B's Outpatient Prospective Payment System (OPPS). *See* 42 U.S.C. § 1395l(t)(2); 65 Fed. Reg. 18434, 18436 (April 7, 2000). Similar to Medicare Part A, Medicare Part B's OPPS typically reimburses drugs dispensed in OPDs on a "package" basis under an Ambulatory Payment Classification System, which is comprised of all items and services for that procedure, identified by their individual J-codes and/or other HCPCS codes—meaning that under the OPPS, Medicare Part B pays for all items and services related to

a procedure with a lump sum—not for individual drugs based on claims made under J-codes. *See* 42 U.S.C. § 1395l(t)(2); 42 C.F.R. §§ 419.21, 419.31; addenda to 65 Fed. Reg. 18434 (April 7, 2000).

United States' Response: Undisputed.

153. Because Novation's membership consists almost exclusively of hospitals, and given the structure of the Medicare regulatory scheme, it is unlikely that very many NovaPlus ipratropium bromide prescriptions were reimbursed under the Medicare program. (Tab 45, 5-18-09 Scott Morton Dep. 341-44, 346-48.)

United States' Response: Undisputed.

154. According to plaintiffs' expert, Dr. Mark G. Duggan, "Roxane's NovaPlus products, at least for Medicaid, account for a minuscule share of all Medicaid prescriptions for ipratropium bromide." (Tab 18, 3-5-09 Duggan Dep. 187.) Dr. Duggan uncovered only 48 NovaPlus ipratropium bromide prescriptions paid for by the Medicaid program throughout the entire United States during the six-year period that NovaPlus ipratropium bromide was sold. (*Id.* 186-188; Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 127.)

United States' Response: Undisputed.

155. Dr. Duggan estimated, based on an extrapolation from the number of Medicaid prescriptions that perhaps only 150 NovaPlus ipratropium bromide prescriptions were reimbursed out of the 12.8 million ipratropium bromide prescriptions paid for under Medicare Part B over the same span. (Tab 18, 3-5-09 Duggan Dep. 188; Tab 20, 5-18-09 Duggan Dep. 156-57; Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 127.)

United States' Response: Undisputed.

C. The DMERCs' Inconsistent And Private Procedures For Constructing Pricing Arrays And Establishing Payment Rates.

156. HCFA and later CMS delegated the task of setting the maximum reimbursement rate for Medicare Part B drugs dispensed via durable medical equipment (DME) to private contractors called durable medical equipment regional carriers (DMERCs). *See* 42 U.S.C. § 1395m(a)(12); 42 C.F.R. § 421.210. The country is divided into four DME regions and each DMERC, following HCFA/CMS guidelines, sets the maximum Medicare rate for DME drugs within its region. *See* 42 U.S.C. § 1395m(a)(12); 42 C.F.R. § 421.210; http://www.ezdme.com/aboutez/dmerc_regions.htm.

United States' Response: The United States disputes the first sentence as imprecise. The DMERCs perform bill processing and benefit payment functions for the Durable Medical

Equipment ("DME") benefit of the Medicare Part B program. Congress and/or CMS establish the laws and regulations that govern payment for services and drugs. CMS also provides periodic instructions to the DMERCs. The DMERCs determine whether services and drugs are covered under Medicare, and determine correct payment amounts for services and drugs in accord with laws, regulations and guidance from CMS. 52 Fed. Reg. 37,526, at 37,527 (October 7, 1987)

157. During the pertinent time period there were four DMERCs that processed ipratropium bromide claims under Medicare Part B. (Tab 50, 2-29-08 Stone Dep. 422-23.) The four DMERCs were generally known as DMERC-A, AdminaStar Federal, Palmetto, and CIGNA. (Tab 18, 3-5-09 Duggan Dep. 130-31.)

United States' Response: The statement is not precisely accurate; for present purposes it is undisputed.

158. Throughout the relevant period, in order to maintain oversight and facilitate compliance with the applicable regulations, HCFA and CMS would issue program memoranda to the carriers, including the DMERCs, which were "instruction[s] to our carriers who administer the Medicare program." (Tab 40, Niemann Dep. 365; *see also* Tab 51, 4-25-07 Tawes Dep. 435 ("A program memorandum is a memo sent to intermediaries or carriers by CMS headquarters").)

United States' Response: Undisputed.

159. By regulation, when pricing drugs for reimbursement purposes under Medicare Part B, the DMERCs were required to utilize the lesser of the "median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological." 42 C.F.R. § 405.517 (emphasis added); *see also* Tabs 167-168, Roxane Exs. 41 and 42, AWQ025-0722 and AWQ025-0880 (Medicare Professional Reimbursement Desk Procedure - Drug Pricing Procedure).

United States' Response: Undisputed as to the time period January 1, 1998, through December 31, 2003. 63 Fed. Reg. 58,814, 58,905 (Nov. 2, 1998)

160. Each of the DMERCs independently set maximum reimbursement rates for its region by consulting the pricing compendia, converting the published AWPs of the drugs selected from the compendia into unitized prices by dividing the published AWPs by the quantity or strength of the packaged drug, compiling those prices into worksheets called pricing arrays,

and then calculating the median price of these arrays. (Tab 22, 8-26-08 Eiler Dep. 47-49, 116; Tab 30, Helton Dep. 22-23; Tab 167, Roxane Ex. 41 at AWQ025-0722– AWQ025-0725 (Drug Pricing Procedure); Tab 169, Roxane Ex. 100 at AWP034-0462–AWP034-0466 (Drug Pricing Procedure); Tab 170, Abbott Ex. 524 at HHD008-0282– HHD008-0287 (Medicare Professional Reimbursement Desk Procedure).)

United States' Response: Undisputed, except that the word "independently" is inaccurate. The DMERCs followed instructions from CMS. In addition, after 1997, the four DMERCs coordinated quarterly to maximize national consistency in their pricing determinations. (Henderson Common Exhibit 3 (Declaration of Carolyn Helton ("Helton Decl.")), ¶ 9)

161. When the median AWP of the generic sources of a drug and the lowest AWP for a brand source were equivalent, the DMERCs used one of the prices as the maximum allowable rate, but could not tell which price actually set the reimbursement rate. (Tab 30, Helton Dep. 230-31; Tab 49, 2-28-08 Stone Dep. 194.)

United States' Response: Undisputed, except that the United States disputes any implication that this paragraph is material to any issue in this case, as there is no factual scenario in this litigation in which the median AWP of the generic sources of any Subject Drug is equivalent to the lowest AWP of a brand source of the drug.

162. The DMERCs' arrays and classification of drugs were not publicly available. (Tab 22, 8-26-08 Eiler Dep. 157-58.)

United States' Response: Disputed to the extent such documents were available pursuant to the Freedom of Information Act, 5 U.S.C. § 551

163. Although HCFA directives to the DMERCs allowed for consideration of a wide variety of published sources, such Red Book, Blue Book, or Medispan, in practice the DMERCs limited their review exclusively to the Red Book compendium. (*See, e.g.*, Tab 171, Abbott 1015, HHC021-0030, December 1998 HCFA Transmittal; Tab 22, 8-26-08 Eiler Dep. 27-28, 47-48, 116-19, Tab24, 9-23-08 Eiler Dep. 481-82; Tab 30, Helton Dep. 22-23, 36, 37; Tab 49, 2-28-08 Stone Dep. 34-35, 65-66, 87-88; Tab 183, Decl. of C. King ¶ 7; Tab 172, Roxane Ex. 51 at AWQ029-00326–AWQ029-00328 (Uniform Drug Pricing Project).)

United States' Response: Undisputed insofar as the Subject Drugs are concerned.

164. During the relevant period, the four DMERCs updated their pricing arrays at different times, and also selected prices from different Red Book sources that were not always consistent. (Tab 22, 8-26-08, Eiler Dep. 125-26, 135-36; Tab 30, Helton Dep. 108, 224-26, 237; Tab 50, 2-29-08 Stone Dep. 284-86.) For example, sometimes one DMERC would receive a monthly update earlier than the other DMERCs, so they would use the update while the other DMERCs would use an outdated version. (Tab 22, 8-26-08 Eiler Dep. 135-36; Tab 30, Helton Dep. 158-59.)

United States' Response: The United States disputes Roxane's characterization of the evidence. The four DMERCs updated their pricing determinations quarterly. (Henderson Common Exhibit 3 (Helton Decl.), ¶ 9) They selected prices from Red Book sources. (*Id.; see also* Fauci Exhibit 163 (Declaration of Robin Stone) (hereinafter "Stone Decl."), ¶ 10) The United States admits that there was not perfect uniformity in precisely which versions of Red Book publications the DMERCs used at any given point in time, and that occasional differences occurred in the DMERCs' determinations of which NDCs to include in their quarterly pricing arrays. However, the DMERCs coordinated their pricing determinations on a quarterly basis, followed the same procedures, and achieved a good degree of national consistency. (Fauci Exhibit 164 (2/29/2008 Robin Stone Dep.), at 301 - 303; Fauci Exhibit 165 (8/26/2008 Cheryl Eiler Dep.), at 153; Fauci Exhibit 166 (HHS OIG report, *DMERCs – Meeting HCFA's Objectives*, OEI-04-97-00330 (February 2000)) Responding further, the United States disputes any suggestion that differences in pricing determinations are relevant or material to this litigation because (a) minor differences in the mechanics of pricing determinations were foreseeable; (b) Roxane was never misled into thinking the DMERCs made pricing determinations with perfect consistency; (c) Roxane never relied on any belief or assumption about the uniformity of DMERC calculations in reporting AWPs; and (d) there was no law or CMS instruction that required or expected perfect uniformity in the DMERCs' quarterly pricing determinations.

165. The inconsistent use of different versions of Red Book sometimes resulted in drugs being omitted from a DMERC's array in one quarter and then reappearing in a later quarter. (Tab 23, 8-27-08 Eiler Dep. 280-86, 295-96.)

United States' Response: The United States disputes the materiality of this statement, as there is no evidence that this occurred in connection with the pricing arrays used to determine reimbursement for ipratropium bromide. Further answering, *see supra* United States' Response to Paragraph 164.

166. The DMERCs varied widely in the sources of Red Book that they relied upon, with some DMERCs using the annual update, others consulting the monthly updates or quarterly electronic CDs, and others using both at times. (Tab 22, 8-26-08 Eiler Dep. 47-48, 125-26, 133-34; Tab 24, 9-23-08 Eiler Dep. 481-82; Tab 30, Helton Dep. 44-45, 224-26; Tab 49, 2-29-08 Stone Dep. 113; Tab 50, 2-29-08 Stone Dep. 284-85; Tab 183, Decl. of C. King ¶¶ 7, 9; Tab 168, Roxane Ex. 42 at AWQ025-0876–AWQ025-0887 (12-1-99 Ltr. from R. Stone to C. Carpenter).)

United States' Response: The United States disputes the characterization of the evidence, and in particular the assertion that the DMERCs "varied widely" in their practices. The DMERCs used the Red Book and relied on the accuracy of the AWPs published therein. (Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 9-10) The DMERCs used the annual Red Book prior to 1999, and Red Book quarterly CD-ROM updates thereafter. (*Id.*; *see also* Fauci Exhibit 167 (8/27/2008 Eiler Dep.), at 292:19 - 293:9; Fauci Exhibit 168 (3/13/2008 Helton Dep.), at 147:7 - 147:17) All four DMERCs calculated the exact same allowable amounts for the K0518 and J7644 ipratropium bromide HCPCS codes ($3.52 before 1998, and $3.34 afterwards) throughout the relevant time period. Further answering, *see supra* United States' Response to Paragraph 164.

167. Each DMERC separately decided how to construct the arrays by reviewing the descriptions in the compendia, and by also consulting other external resources such as reference guides and medical directors that each DMERC had on staff and by exercising their judgment. (Tab 22, 8-26-08 Eiler Dep. 27, 48-49, 58-59, 119-20, 149, Tab 24, 9-23-08 Eiler Dep. 487-88; Tab 30, Helton Dep. 89, 160-61; Tab 49, 2-28-08 Stone Dep. 77-78, 86, Tab 50, 2-29-08 Stone

Dep. 275-76; Tab 53, 8-27-08 Eiler Dep. Roxane Ex. 41 at AWQ025-0722–AWQ025-0725 (Drug Pricing Procedure).)

United States' Response: The phrase "separately decided how to construct the arrays by reviewing the descriptions in the compendia" is ambiguous as used in this paragraph. The United States does not dispute that some of the DMERCs consulted sources including the Physician's Desk Reference in determining which NDCs to include in the pricing array for a particular HCPCS code. The paragraph is otherwise disputed, and is not supported by the cited authority. The United States also disputes the materiality of this statement, as there is no evidence that the DMERCs consulted any so-called "external sources" in creating the pricing arrays used to determine reimbursement for ipratropium bromide. Further answering, *see supra* United States' Response to Paragraph 164.

168. At times the narrative description of a drug in Red Book was not clear enough for the DMERCs to determine whether to include the drug in their pricing arrays, which meant that sometimes the DMERCs had to use their own judgment in making that determination. (Tab 24, 9-23-08 Eiler Dep. 487.)

United States' Response: The United States does not dispute that Ms. Eiler testified that, at times, the narrative description of a product contained in the Red Book was not "always perfectly clear" and that, therefore, she on occasion looked to other sources including the Physician's Desk Reference in determining whether to include particular NDCs in the pricing array for a given HCPCS code. (Tab 24, at 487) The paragraph is otherwise disputed, and is not supported by the cited authority. Further answering, the United States disputes the materiality of this statement, as there is no evidence that the narrative descriptions contained in the Red Book were "not clear enough" for the DMERCs to determine which NDCs to include in the pricing arrays for ipratropium bromide.

169. As such, DMERCs did not consistently include all forms of a drug in their arrays. (Tab 22, 8-26-08 Eiler Dep. 48, 147-148, Tab 24, 9-23-08 Eiler Dep. 487-88; Tab 30, Helton Dep. 150-51; Tab 50, 2-29-08 Stone Dep. 298-299)

United States' Response: The United States does not dispute that the DMERCs excluded certain forms of drugs from their pricing arrays. Specifically, the DMERCs generally excluded drugs with special packaging or convenience items such as flip-top vials or carpu-jets because these items were not considered necessities and tended to inflate prices. (Fauci Exhibit 167 (4/27/2008 Eiler Dep.), at 360:4 - 360:12; Fauci Exhibit 168 (3/13/2008 Helton Dep.), at 150:11 - 151:17; Henderson Common Exhibit 3 (Helton Decl.), ¶ 10) The paragraph is otherwise disputed, and is not supported by the cited authority. Further answering, the United States disputes the materiality of this statement, as there is no evidence that this occurred in connection with the pricing arrays for ipratropium bromide.

170. The AdminaStar Federal DMERC acknowledged this divergence, stating that other DMERCs "did things a little different than we did." (Tab 22, 8-26-08 Eiler Dep. 128.)

United States' Response: The United States does not dispute that Ms. Eiler testified that the AdminaStar DMERC "did things a little different than" the Palmetto DMERC. Further answering, the phrase "acknowledged this divergence" is ambiguous as used in this paragraph and, in any event, the cited authority does not support a finding or inference that there was a "divergence" in the DMERCs' pricing determinations. As noted *supra* in the United States' Response to Paragraph 164, the DMERCs coordinated their pricing determinations on a quarterly basis, followed the same procedures, and achieved a good degree of national consistency.

171. The DMERCs noted in correspondence with HCFA that they had issues "determining the correct forms of the drugs to pickup from REDBOOK," and asked HCFA to make program memoranda "more specific in what items should be excluded and/or included in the calculation" in order to "help eliminate the wide interpretations by different carriers." (Tab 172, Roxane Ex. 51 at AWQ029-00327 (Uniform Drug Pricing Project); *see also* Tab 30, Helton

Dep. 160-61.)

United States' Response: The United States does not dispute that various of the DMERCs at times had questions in determining which NDCs to include in a pricing array for a particular HCPCS code. (Tab 30, p. 160-61) The United States also does not dispute that Roxane has correctly, but selectively, quoted excerpts from the document entitled "Uniform Drug Pricing Project." The United States disputes the materiality of this paragraph, however, as there is no evidence that the DMERCs experienced any difficulty or confusion in selecting which NDCs to include in the pricing arrays for ipratropium bromide.

172. Although the DMERCs at times contacted manufacturers to verify prices for durable medical equipment, they never contacted the manufacturers to verify the pricing for drugs listed in Red Book. (Tab 22, 8-26-08 Eiler Dep. 73.)

United States' Response: The United States does not dispute that Ms. Eiler testified that the AdminaStar DMERC did not contact manufacturers to obtain AWPs. The paragraph is otherwise disputed, and is not supported by the cited authority. Further answering, the DMERCs relied upon the AWPs published in the Red Book. (Henderson Common Exhibit at (Helton Decl.), ¶¶ 9, 26; *see also* Fauci Exhibit 169 (2/28/2008 Stone Dep.), at 34:9 - 34:17, 112:10 - 113:8; Fauci Exhibit 165 (8/26/2008 Eiler Dep.), at 27:10 - 28:2; Fauci Exhibit 168 (3/13/2008 Helton Dep.), at 21:21 - 23:17)

173. Because of the historic variance in payment rates across DMERCs for the same drugs, beginning in approximately 1997, continuing with the "Uniform Drug Pricing Project" in 1999, and again in 2001, the DMERCs consulted and shared information with each other to reduce inconsistencies—usually without any participation by HCFA/CMS. (Tab 22, 8-26-08 Eiler Dep. 127-28, 135-36, 153-54, 166-67, 171-72; Tab 30, Helton Dep. 99-100, 144-46, 169-71, 277-78; Tab 50, 2-29-08 Stone Dep. 282-83; Tab 183, Decl. of C. King ¶ 17; Tab 168, Roxane Ex. 42 at AWQ025-0876–AWQ025-0887 (12-1-99 Ltr. from R. Stone to C. Carpenter); Tab 172, Roxane Ex. 51 at AWQ029-00326–AWQ029-00328 (Uniform Drug Pricing Project); Tab 173, Roxane Ex. 52 at AWQ029-000104– AWQ029-000105 (5-15-01 E-mail from R. Stone to C. King, C. Eiler, C. Helton, B. Douglas, and V. Brantley); Tab 169, Roxane Ex. 100 at

AWP034-0462–AWP034-0466 (Drug Pricing Procedure); Tab 174, Roxane Ex. 102 at AWP039-1420 (7-6-99 E-mail from C. King to C. Eiler).) The DMERCs did not, however, coordinate their construction of arrays or ensure that all four DMERCs were using the same published prices or classifying drugs in an identical way. (Tab 22, 8-26-08 Eiler Dep. 153-54; Tab 30, Helton Dep. 108-09, 144-46; Tab 172, Roxane Ex. 51 at AWQ029-00326– AWQ029-00328 (Uniform Drug Pricing Project; Tab 174, Roxane Ex. 102 at AWP039-1420 (7-6-99 E-mail from C. King to C. Eiler).)

United States' Response: The United States does not dispute that the DMERCs consulted and shared information in an effort to increase consistency. (Henderson Common Exhibit 3 Helton Decl., ¶ 9) The United States also admits that the DMERCs did not achieve perfect uniformity in their pricing determinations. The paragraph is otherwise disputed, and is not supported by the cited authority. Further answering, the DMERCs regularly consulted with CMS, and made decisions in accordance with applicable laws and regulations as well as CMS guidance. (*Id.*, ¶¶ 8, 10, 12-13)

D. HCFA's Regulations And Directives Distinguished Generics From Brands Based On Whether The Drug Used Its Generic Chemical Name.

174. On November 2, 1998, HCFA implemented a final rule that revised its payment methodology for generics under Medicare Part B to include consideration of AWPs for brand drugs. *See* 63 Fed. Reg. 58813, 58849 (1998) (Tab 112, Abbott Ex. 209). HCFA adopted a payment formula for generic drugs that required Medicare carriers, including the DMERCs, to compare "the lower of the median price of the generic AWPs" with "the lowest brand name AWP," and then pay the lower amount. *Id.*; *see also* 42 CFR § 405.517 (1998).

United States' Response: The word "generic" as used in the first sentence of this paragraph is ambiguous. The United States does not dispute that in November 1998, CMS implemented a final rule revising its payment methodology for multi-source drugs. In comments to the proposed rule published in the Federal Register on June 5, 1998, CMS noted:

> Our current regulations provide that, for multiple-source drugs, the AWP equals the median AWP of the generic forms of the drug. The AWP of the brand name products is ignored on the presumption that brand AWP is always higher than the generic AWPs. While this may have been true when the policy was first

> promulgated, it is not always true now. Therefore, we are proposing that the AWP for multiple-source drugs would equal the lower of the median price of the generic AWPs or the lowest brand name AWP.

(63 Fed. Reg. 30,818, at 30,845 (June 5, 1998)) The proposed rule became final in November 1998. Effective that date, 42 C.F.R. § 405.517(c) provided that:

> [f]or multiple source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological *or the lowest average wholesale price of the brand name forms of the drug or biological*.

(emphasis supplied). As a result of comments made during the rulemaking process, CMS adopted 42 C.F.R. § 405.517(c) with several clarifications including, *inter alia*, that "[a] 'brand' product is defined as a product that is marketed under a labeled name that is other than the generic chemical name of the drug or biological." (63 Fed. Reg. 58,814, at 58,849-50) CMS specifically considered and rejected a definition of "brand" that was limited to the product of the innovator company:

> Comment: One commenter stated that our definition of "brand" should be "the product of the innovator company." The commenter objected to considering other manufacturers' products that are marketed under a proprietary name other than the generic chemical name of the drug as a "brand."
>
> Our definition of "brand" is any product that is marketed under a name other than the generic chemical name of the drug. *If a manufacturer chooses to market its product under a proprietary name rather than the generic chemical name of the drug, we believe this is a brand. We do not limit the definition of "brand to the innovator company product or any product manufactured under a direct license from the innovator.* Furthermore, we believe that it is an unreasonable administrative burden to require our contractors to determine which of the thousands of AWPs they must look up, to determine which of those are innovator drugs or licensed by the innovator company.

Id. (emphasis supplied).

175. In response to a comment generated during the rulemaking process, HCFA provided the following definition of what it considered to be a "brand" for purposes of Medicare

Part B payments:

> Our definition of "brand" is any product that is marketed under a name other than the generic chemical of the drug. If a manufacturer chooses to market its product under a proprietary name rather than the generic chemical name of the drug, we believe this is a brand . . . . A "brand" product is defined as a product that is marketed under a labeled name that is other than the generic chemical name of the drug or biological.

(Tab 112, Abbott Ex. 209).

United States' Response: Undisputed. Further answering, the language Roxane cites in this paragraph is incomplete. *(See supra* United States' Response to Paragraph 174)

176. HCFA also included a near-identical definition of "brand" as in the regulation in a program memorandum issued to carriers following the regulation: "A 'brand name' product is defined as a product that is marketed under a labeled name that is other than the generic chemical name for the drug or biological." ((Tab 171, Abbott Ex. 1015 at HHC201-0030 (HCFA Program Memorandum, Transmittal No. AB-98-76; Tab 175, Abbott Ex. 529 at AWQ025-1349 (HCFA Program Memorandum, Transmittal No. AB-98-76).)

United States' Response: Undisputed. Further answering, the program memorandum stated as follows:

> For a multi-source drug or biological, the AWP is equal to the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product. AWP. A "brand name" product is defined as a product that is marketed under a labeled name that is other than the generic chemical name for the drug or biological.

(Tab 171)

177. The Medicare Supplier Bulletin that preceded the November 1998 regulation also illustrated this distinction by including a table listing generic names in one column and the corresponding trade/brand names in the next. (Tab 176, Eiler Ex. 6 at AWQ058-0950, ("Medicare Supplier Bulletin Region B DMERC"); Tab 177, Dey Ex. 126 at HHD011-0223, ("CIGNA DMERC: Nebulizer Medications".) One of the entries explicitly listed "ipratropium bromide" as the "generic" and "Atrovent" as the corresponding "trade/brand" name. (Tab 176, Eiler Ex. 6 at AWQ058-0950, ("Medicare Supplier Bulletin Region B DMERC"); Tab 177, Dey Ex. 126 at HHD011-0223, "CIGNA DMERC: Nebulizer Medications".) In every instance, the trade/brand example was comprised solely of a proprietary trade name, and did not include the underlying chemical compound in the name of the drug. (Tab 176, Eiler Ex. 6 at AWQ058-0950,

("Medicare Supplier Bulletin Region B DMERC"); Tab 177, Dey Ex. 126 at HHD011-0224, ("CIGNA DMERC: Nebulizer Medications".)

United States' Response: Disputed. The referenced section of the Medicare Supplier Bulletin provides instructions on coding guidelines for "compounded products." The guidelines include a table listing "generic names of drugs which are compounded in inhalation solutions and some corresponding brand/trade names." (Tab 176, at AWQ058-0950) The column listing the "trade/brand" names states that it is "not an all inclusive list." (*Id.*) All of the products listed in the "generic" table include *only* the generic ingredient name and do not include any proprietary or trade names such as "NOVAPLUS." (*Id.*)

178. In December 1998, HCFA issued a Program Memorandum that directed the Medicare DMERCs to implement the November 1998 regulatory changes. (Tab 171, Abbott Ex. 1015 at HHC201-0030 (HCFA Program Memorandum, Transmittal No. AB-98-76); Tab 175, Abbott Ex. 529 at AWQ025-1349 (HCFA Program Memorandum, Transmittal No. AB-98-76).) HCFA directed the carriers to obtain published AWPs from "sources such as the Red Book, Blue Book, or Medispan." (*Id.*)

United States' Response: Undisputed. *See supra* United States' Response to Paragraph 176.

E. The DMERCs' Idiosyncratic And Private Classification Criteria Ignored And Were Inconsistent With HCFA's Regulatory Definitions And Directives.

179. Throughout the relevant period the DMERCs constructed separate arrays for generic and brand versions of ipratropium bromide to determine whether the median of the generic AWPs was lower than the lowest brand AWP. (Tab 24, 9-23-08 Eiler Dep. 547; Tab 18, 3-5-09 Duggan Dep. 146)

United States' Response: The United States does not dispute that the DMERCs constructed quarterly pricing arrays for ipratropium bromide. Further answering, the arrays contained sections separately listing the AWPs for generic and brand products.

180. In determining whether a drug was a generic versus a brand, the DMERCs' Medicare Professional Reimbursement Desk Procedures, Drug Pricing Procedure ("Drug Pricing Procedure") did not use the regulatory definition that a "brand" product is defined as a product that is marketed under a labeled name that is other than the generic chemical name of the drug or

biological." (Tab 22, 8-26-08 Eiler Dep. 145-46, Tab 24, 9-23-08 Eiler Dep. 485, 547-49 ("Q: Now I want to suggest to you, Ms. Eiler that Novaplus actually has always been a generic product, not a brand product. And that if one – I want you to assume that if one had done additional research, the generic status of that drug might have been discovered . . ."), 558-603 ("Q: Okay. I'd like you to assume today that in fact they're [Novaplus NDCs] generic drugs, and that if you have done some additional research, besides just looking at the RedBook, you might have determined that they were in fact generics."); Tab 30, Helton Dep. 253-54; Tab 168, Roxane Ex. 42 (12-1-99 Ltr from R Stone to C. Carpenter), Tab 169, Roxane 100 (Drug pricing Procedure).) Instead, the Medicare Professional Reimbursement Desk Procedures, Drug Pricing Procedure directed the DMERCs to use the following methodology to determine whether a drug was a brand drug:

> To determine if a drug is generic or brand, look at the bold face upper case name of the drug [in the Drug Topics Red Book publication]. If there is another name for the drug immediately below it in lower case letter (the generic name), the entries following are generally brands. If there is no lower case drug name immediately below the bold face upper case name, the bold face upper case name is the generic name and all the entries below are generics. In either case, if an entry below the drug name refers to another page, that entry would be for a brand name. If there is a question as to whether a drug is brand or generic, consult the PDR Generics, telephone the drug company or **Red Book** (1-800-222-3045).

(Tab 168, Roxane Ex. 42 at AWQ025-0881-82, (12-1-99 Letter from R. Stone to C. Carpenter – Drug Pricing Procedure) (emphasis in original); (*see also* Tab 22, 8-26-08 Eiler Dep. 145-46; Tab 24, 9-23-08 Eiler Dep. 485, 547-49; Tab 169, Roxane 100 (Drug Pricing Procedure).

United States' Response: The United States does not dispute that the Medicare Professional Reimbursement Desk Procedure, Drug Pricing Procedure ("Drug Pricing Procedure") includes the quoted language. The paragraph is otherwise disputed, and Roxane offers no evidence to support a finding that "the DMERCs did not use the regulatory definition that a 'brand' product is defined as a product that is marketed under a labeled name that is other than the generic chemical name of the drug or biological." Further answering, the evidence establishes that during the time period when Roxane's NovaPlus ipratropium bromide products were used in the arrays, the DMERCs classified products as brands based on whether they had label names other than the generic chemical name of the drug. (Fauci Exhibit 163 (Stone Decl.), ¶ 8; Henderson

Common Exhibit 3 (Helton Decl.),¶¶ 28-29)

The DMERCs utilized the Red Book to access AWPs. (Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 9, 26; *see also* Fauci Exhibit 169 (2/28/2008 Stone Dep.), at 34:9 - 34:17, 112:10 - 113:8; Fauci Exhibit 165 (8/26/2008 Eiler Dep.), at 27:10 - 28:2; Fauci Exhibit 168 (3/13/2008 Helton Dep.), at 21:21 - 23:17) Prior to 1999, the DMERCs used the annual printed version of the Red Book; beginning in 1999, the DMERCs accessed the Red Book electronically via quarterly CD-ROM updates. (Fauci Exhibit 163 (Stone Decl.), ¶ 10; Fauci Exhibit 167 (8/27/2008 Eiler Dep.), at 292:19 - 293:9; Fauci Exhibit 168 (3/13/2008 Helton Dep.), p. 147:7 - 147:17)

The Drug Pricing Procedure was created in 1995 and was updated from time to time. (Tab 168) The version of the Drug Pricing Procedure last updated June 25, 1999 stated that the DMERCs should refer to the annual Red Book's capitalization and typeface conventions in determining if a product was a brand or a generic. (*Id.*) These instructions were inapplicable to the DMERCs' classification of NovaPlus because, by 1999, the DMERCs were utilizing the electronic CD-ROM version of the Red Book. (Fauci Exhibit 163 (Stone Decl.), ¶ 10; Fauci Exhibit 167 (8/27/2008 Eiler Dep.), at 292:19 - 293:9; Fauci Exhibit 168 (3/13/2008 Helton Dep.), at 147:7 - 147:17) The electronic CD-ROM version of the Red Book had different capitalization and typeface conventions as compared to the annual printed Red Book. (Fauci Exhibit 163 (Stone Decl.), ¶11) The DMERCs used a search function on the CD-ROM to retrieve the brand and generic products for a given drug into a "Product Information Screen." (Henderson Common Exhibit 3 (Helton Decl.), ¶ 31) The typeface and font in the Product Information Screen were the same for both brands and generics. (*Id.*; *see also* Tabs 179 and 180

(which are representative printouts from the Product Information Screen of quarterly CD-ROM updates to the Red Book)).

When the DMERCs uploaded a new quarterly CD-ROM, the data relating to the prior quarter was programed to automatically become inaccessible. (*See infra* Paragraph 211; *see also* Fauci Exhibit 167 (8/27/2008 Eiler Dep.), at 293:17 - 295:11; Fauci Exhibit 170 (3/12/2008 Walker Dep.), at 156:15 - 157:3) An employee at one DMERC, however, had a practice of printing out pages from the quarterly CD-ROM Red Book updates whenever there were changes in the reported prices. (Fauci Exhibit 167 (8/27/2008 Eiler Dep.), at 293:17 - 295:11) A printout from the April 2002 Red Book CD-ROM describes Roxane's generic ipratropium bromide product as "IPRATROPIUM BROMIDE" and Roxane's Nova-Plus ipratropium bromide as "IPRATROPIUM BROMIDE - NOVAPLUS." (Tab 180) This is consistent with how other NovaPlus products (i.e., non-ipratropium bromide NovaPlus products) appear in other Product Information Screens printed out from the quarterly CD-ROM Red Book updates. (Fauci Exhibit 171)

During the relevant time period, the CIGNA and Palmetto DMERCs generally classified products including "NovaPlus" in the product name as brands, including NovaPlus products other that NovaPlus ipratropium bromide. (*See* Fauci Exhibit 163 (Stone Decl.), ¶ 9 and Exhibit C thereto; Henderson Common Exhibit 3 (Helton Decl.), ¶ 30, and Exhibit E thereto, at AWQ020-000887 (classifying "Vepesid NovaPlus" as a brand), AWQ012-0498 (classifying "Bleomycin NovaPlus" as a brand)) The DMERCs classified products that included "NovaPlus" as part of the product name as brands because such products had label names other than the generic chemical name of the drug. (Fauci Exhibit 163 (Stone Decl.), ¶¶ 8-9; Henderson

Common 3 (Helton Decl.),¶¶ 29-30)

181. The DMERCs sometimes determined whether a drug was a brand by whether it had the word "See" in the Red Book, indicating a cross reference. (Tab 30, Helton Dep. 253-54)

United States' Response: The United States does not dispute that Ms. Helton testified that in the 1997 time frame, she considered the fact that a product name was preceded by the word "see" in the annual printed Red Book as an indication that a product was a brand. (Tab 30, p. 252:8 - 254:5) The United States disputes the materiality of this paragraph, however, as the annual printed Red Book was not used to determine whether NovaPlus ipratropium bromide was a brand, because the DMERCs were using CD-ROM updates to the Red Book by 1999. (*See supra* United States' Response to Paragraph 180; *see also* Henderson Common Exhibit 3 (Helton Decl.), ¶ 31)

182. The DMERCs also sometimes made the brand/generic classification without consulting the printed Red Book. (Tab 24, 9-23-08 Eiler Dep. 600-03.) On those occasions, DMERCs would review certain files on a Red Book CD database that did not have the same capitalization convention as the printed volumes but instead listed the brand drugs in separate data files. (*Id*.; Tab 50, 2-29-08 Stone Dep. 305-310.)

United States' Response: The United States does not dispute that from 1999 onwards, the DMERCs made decisions about how to classify drugs without consulting the annual printed version of the Red Book. Instead, the DMERCs used the quarterly electronic CD-ROM updates to the Red Book to access AWPs, (*see supra* United States' Response to Paragraph 180), and classified products as brands according to whether they had label names other than the generic chemical name of the drug. (Fauci Exhibit 163 (Stone Decl.), ¶ 8-9; Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 29-31) Printouts from the Product Information Screen on the CD-ROM Red Book updates listed products by their full label name. (*See supra* United States' Resp to Paragraph 180; Henderson Common Exhibit 3 (Helton Decl.), ¶ 31). Further answering, the

phrase "instead listed the brand drugs in separate data files" as used in the second sentence of this paragraph is ambiguous. The remainder of the paragraph is disputed, and is not supported by the cited authority.

183. Once a DMERC made the initial determination of whether a drug was a generic or a brand, the DMERC would carry that same classification through in subsequent quarters unless "some notation in the RedBook . . . indicated it had changed from branded to generic or vice versa." (Tab 24, 9-23-08 Eiler Dep. 603.)

United States' Response: The United States admits that once the DMERCs classified a product as a generic or brand, the classification generally carried through unless the DMERCs learned of a change in the product name. The paragraph is otherwise disputed, and is not supported by the cited authority.

184. The Annual Red Book did not begin listing the NDCs for the NovaPlus label ipratropium bromide inhalation solution until 2001. (*Compare* Tab 154, 2001 RedBook at 368 *with* Tab 178, 2000 Red Book at 369.)

United States' Response: Undisputed. Further answering, Roxane's NovaPlus ipratropium bromide product was first classified as a brand by the AdminaStar DMERC in the third quarter of 2000. This demonstrates that the annual printed version of the Red Book played no role in the decision of whether to classify NovaPlus ipratropium bromide as a brand. (*See supra* United States' Response to Paragraph 180).

185. In the 2001 Annual Red Book, under the bold-faced, upper-case **IPRATROPIUM BROMIDE** heading in the left-hand column, the Red Book listed all ipratropium products by manufacturer. (Tab 154, 2001 Red Book at 368.) For example, under the **IPRATROPIUM BROMIDE** heading it listed generic ipratropium bromide products by **(Alpharma USPD), (Dey), (Roxane)** and **(Zenith Goldline)**. (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book

did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

186. The 2001 Annual Red Book listed the three NovaPlus label ipratropium bromide NDCs (0054-8404-11, 0054-8404-13, 0054-8404-21) directly underneath to the Roxane label ipratropium bromide NDCs (0054-8402-11, 0054-8402-13, 0054-8402-21). (*Id.*) All six NDCs were listed under the "**(Roxane)"** manufacturer designation. (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

187. The 2001 Annual Redbook listed identical AWPs for the three Roxane label NDCs and the corresponding NovaPlus label NDCs of the same package sizes. (*Id.*) For example, the Roxane-label 2500 ml 25s unit dose vial (NDC 00054-8402-11) listed an AWP of 44.06; the NovaPlus-label 2500 ml 25s unit dose vial (NDC 00054-8404-11) listed the same AWP of 44.06. (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly

classified NovaPlus ipratropium bromide as a brand.

188. The 2001 Annual Red Book descriptions for the three NovaPlus label NDCs were identical to the corresponding package sizes for the three Roxane label NDCs. For example, all six NDCs contained the description "SOL, IH (S.D.V. […] PROTECTAPAK 0.02%." (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

189. The 2001 Annual Red Book listings for the NovaPlus-label NDCs did not contain the word "NovaPlus" anywhere under any of the **IPRATROPIUM BROMIDE** listings or **(Roxane)** NDC sub-listings. (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

190. The 2001 Annual Red Book listings for the NovaPlus label NDCs did not contain the word "See" next to the NovaPlus label or Roxane label NDCs. (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the

Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

191. The 2001 Annual Red Book contained a listing under the **IPRATROPIUM BROMIDE** heading that read as follows: **(Boehr Ingelheim)** *See ATROVENT.* (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

192. The 2001 Annual Red Book listing for the Roxane label or NovaPlus label ipratropium bromide did not contain the word "ipratropium bromide" in either bold face or capitals under the **(Roxane)** listing. (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

193. The 2001 Annual Red Book listing did not contain a separate entry for "IPRATROPIUM BROMIDE NOVAPLUS." (*Id*.)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

194. Other than different NDC numbers, the NovaPlus label NDC listings in the 2001 Annual Red Book were identical to the corresponding package sizes of the Roxane-label NDCs. (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

195. The 2001 Annual Red Book listings for the NovaPlus NDCs identified them as generic drugs under the Medicare Professional Reimbursement Desk Procedures, Drug Pricing Procedure (Tab 168, Roxane Ex. 42 at AWQ025-0881-82, 12-1-99 Ltr. from R. Stone to C. Carpenter, Drug Pricing Procedure). There was a "bold face upper case name," (*i.e.*, **IPRATROPIUM BROMIDE**) in the 2001 Annual Red Book listing, but there was not "another name for the drug immediately below it in lower case name letters (the generic name)," and thus the entry did not indicate a brand. (Tab 154, 2001 Red Book at 368; *supra* ¶¶ 46, 51-60.) Because "there is no lower case drug name immediately below" **IPRATROPIUM BROMIDE,** ipratropium bromide "is the generic name and all the entries below are generics." (Tab 168,

Roxane Ex. 42 at AWQ025-0881-82, 12-1-99 Ltr from R Stone to C Carpenter.)

United States' Response: Disputed. Roxane offers no evidence to support a finding that the Drug Pricing Procedure has any bearing on whether or not the NovaPlus ipratropium bromide product was properly classified as a brand product. Further answering, by 1999, the DMERCs were using quarterly CD-ROM updates to the Red Book. (*See* Stone Decl., ¶ 10; Fauci Exhibit 167 (8/27/2008 Eiler Dep.), at 292:19 - 293:9; Fauci Exhibit 168 (3/13/2008 Helton Dep.), at 147:7 - 147:17) The Product Information Screen on the CD-ROM updates to the Red Book listed products by their full name. (Henderson Common Exhibit 3 (Helton Decl.), ¶ 31) For example, the Product Information Screen from the April 2002 Red Book CD-ROM listed ipratropium bromide as "IPRATROPIUM BROMIDE - NOVAPLUS." (Tab 180) The DMERCs classified NovaPlus ipratropium bromide as a brand because it had a labeled name other than the generic chemical name of the drug. (Fauci Exhibit 163 (Stone Decl.), ¶¶ 8-9; Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 29-31) Further answering, *see supra* United States' Response to Paragraph 180.

196. The 2001 Annual Red Book listing for the NovaPlus NDCs identified them as generic drugs according to the criteria used by at least the DMERC for distinguishing brand from generic drugs. (Tab 24, 9-23-00 Eiler Dep. 547-49).

United States' Response: Disputed. Roxane offers no evidence to support a finding that the AdminaStar DMERC used the 2001 annual printed Red Book in classifying NovaPlus ipratropium bromide as a brand. Further answering, *see supra* United States' Responses to Paragraphs 180 and 195.

197. The 2001 Annual Red Book listing for the NovaPlus NDCs identified them as generic drugs according to the criteria used by at least the CIGNA DMERC for distinguishing brand from generic drugs. (Tab 30, Helton Dep. 253-54). Specifically, the word "see" was not next to any of the NovaPlus-NDCs. (Tab 154, 2001 Red Book at 368). According to the CIGNA

DMERC's criteria for identifying brand drugs, the 2001 Annual Red Book listing for "ATROVENT" identified that product as a brand product for ipratropium bromide because it had the word "See" and a cross-reference next to it. (Tab 30, Helton Dep. 253-54).

United States' Response: Disputed. Roxane offers no evidence to support a finding that the CIGNA DMERC used the 2001 annual printed Red Book in classifying NovaPlus ipratropium bromide as a brand. Further answering, *see supra* United States' Responses to Paragraphs 180 and 195.

198. In the 2002 Annual Red Book, under the bold-faced, upper-case **IPRATROPIUM BROMIDE** heading in the left-hand column, the Red Book listed all ipratropium products by manufacturer. (Tab 180, 2002 Red Book at 389) For example, under the **IPRATROPIUM BROMIDE** heading it listed generic ipratropium bromide products by **(Alpharma USPD), (Dey), (Roxane)** and **(Zenith Goldline)**. (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

199. The 2002 Annual Red Book listed the three NovaPlus-label ipratropium bromide NDCs (0054-8404-11, 0054-8404-13, 0054-8404-21) directly underneath to the Roxane label ipratropium bromide NDCs (0054-8402-11, 0054-8402-13, 0054-8402-21). (*Id.*) All six NDCs were listed under the "**(Roxane)"** manufacturer designation. (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed

products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

200. The 2002 Annual Red Book listed identical AWPs for the three Roxane-label NDCs and the corresponding NovaPlus-label NDCs of the same package sizes. (*Id.*) For example, the Roxane-label 2500 ml 25s unit dose vial (NDC 00054-8402-11) listed an AWP of 44.06; the NovaPlus-label 2500 ml 25s unit dose vial (NDC 00054-8404-11) listed the same AWP of 44.06. (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

201. The 2002 Annual Red Book descriptions for the three NovaPlus label NDCs were identical to the corresponding package sizes for the three Roxane-label NDCs. For example, all six NDCs contained the description "SOL, IH (S.D.V. […] PROTECTAPAK 0.02%." (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

202. The 2002 Annual Red Book listings for the NovaPlus label NDCs did not contain the word "NovaPlus" anywhere under any of the **IPRATROPIUM BROMIDE** listings or **(Roxane)** NDC sub-listings. (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

203. The 2002 Annual Red Book listings for the NovaPlus label NDCs did not contain the word "See" next to the NovaPlus label or Roxane label NDCs. (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

204. The 2002 Annual Red Book contained two listings under the **IPRATROPIUM BROMIDE** heading that read as follows: **(Boehr Ingelheim Pharm)** *See ATROVENT.* (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book

did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

205. The 2002 Annual Red Book listing for the Roxane label or NovaPlus label ipratropium bromide did not contain the word "ipratropium bromide" in either bold face or capitals under the **(Roxane)** listing. (*Id*.)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

206. The 2002 Annual Red Book listing did not contain a separate entry for "IPRATROPIUM BROMIDE NOVAPLUS." (*Id*.)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

207. Other than different NDC numbers, the NovaPlus label NDC listings in the 2002

Annual Red Book were identical to the corresponding package sizes of the Roxane-label NDCs. (*Id.*)

United States' Response: Undisputed. However, the United States disputes the materiality of this paragraph because, by 1999, the DMERCs were using the quarterly CD-ROM updates to the Red Book. The Product Information Screen on the quarterly CD-ROM updates to the Red Book did not use typeface or font to distinguish between brands and generics and, instead, listed products by their full name. (*See supra* United States' Response to Paragraph 180) Therefore, the annual printed Red Book is immaterial to the issue of whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand.

208. The 2002 Annual Red Book listings for the NovaPlus NDCs identified them as generic drugs under the Medicare Professional Reimbursement Desk Procedures, Drug Pricing Procedure (Tab 168, Roxane Ex. 42 at AWQ025-0881-82, (Medicare Professional Reimbursement Desk Procedure, Drug Pricing Procedure)). There was a "bold face upper case name," (*i.e.*, **IPRATROPIUM BROMIDE**) in the 2002 Annual Red Book listing, but there was not "another name for the drug immediately below it in lower case name letters (the generic name)," and thus the entry did not indicate a brand. (Tab 180, 2002 Red Book at 389; *supra* ¶¶ 46, 64-73.) Because "there is no lower case drug name immediately below" **IPRATROPIUM BROMIDE,** ipratropium bromide "is the generic name and all the entries below are generics." (Tab 168, Roxane Ex. 42 at AWQ025-0881-82, 12-1-99 Ltr. from R. Stone to C. Carpenter - Drug Pricing Procedure AWQ025-0876-79)).

United States' Response: Disputed. Roxane offers no evidence to support a finding that the Drug Pricing Procedure has any bearing on whether or not NovaPlus ipratropium bromide was properly classified as a brand product. Further answering, by 1999, the DMERCs were using quarterly CD-ROM updates to the Red Book. (*See* Fauci Exhibit 163 (Stone Decl.), ¶ 10; Fauci Exhibit 167 (8/27/2008 Eiler Dep.), at 292:19 - 293:9; Fauci Exhibit 168 (3/13/2008 Helton Dep.), at 147:7 - 147:17) The Product Information Screen on the CD-ROM updates to the Red Book listed products by their full name. (Henderson Common Exhibit 3 (Helton Decl.), ¶ 31) For example, the Product Information Screen from the April 2002 Red Book CD-ROM update

listed ipratropium bromide as "IPRATROPIUM BROMIDE - NOVAPLUS." (Tab 180) The DMERCs classified NovaPlus ipratropium bromide as a brand because it had a labeled name other than the generic chemical name of the drug. (Fauci Exhibit 163 (Stone Decl.), ¶¶ 8-9; Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 29-31) Further answering, *see supra* United States' Responses to Paragraphs 180 and 195.

209. The 2002 Annual Red Book listing for the NovaPlus NDCs identified them as generic drugs according to the criteria used by at least the DMERC for distinguishing brand from generic drugs. (Tab 24, 9-23-08 Eiler Dep. 547-49).

United States' Response: Disputed. Roxane offers no evidence to support a finding that the DMERC used the 2002 annual printed Red Book in classifying NovaPlus ipratropium bromide as a brand. Further answering, *see supra* United States' Responses to Paragraphs 180 and 195.

210. The 2002 Annual Red Book listing for the NovaPlus NDCs identified them as generic drugs according to the criteria used by at least the CIGNA DMERC for distinguishing brand from generic drugs. (Tab 30, Helton Dep. 253-54). Specifically, the word "see" was not next to any of the NovaPlus-NDCs. (Tab 180, 2002 Red Book at 389). According to the CIGNA DMERC's criteria for identifying brand drugs, the 2002 Annual Red Book listing for "ATROVENT" identified that product as a brand product for ipratropium bromide because it had the word "See" next to it. (Tab 30, Helton Dep. 253-54).

United States' Response: Disputed. Roxane offers no evidence to support a finding that the CIGNA DMERC used the 2002 annual printed Red Book in classifying NovaPlus ipratropium bromide as a brand. Further answering, *see supra* United States' Responses to Paragraphs 180 and 195.

211. Each time the DMERCs utilized the quarterly Red Book electronic CD databases by uploading a new electronic CD, the data provided on the previous electronic CD was deleted. (Tab 23, 8-27-08 Eiler Dep. 295.) The DMERCs could not keep a record of the data from the previous electronic CD other than by printing a hard copy. (*Id.*)

United States' Response: The United States does not dispute that the data provided on the quarterly CD-ROM updates to the Red Book was programmed to become inaccessible after a

new CD-ROM was loaded. The paragraph is otherwise disputed, and it is not supported by the cited authority.

212. The few hard copy printouts produced by the DMERCs list *all* drugs—brand and generic—in all-capital letters. (Tab 24, 09-23-08 Eiler Dep. 600-03; Tab 179, AWP039-3207 (July 2000 Red Book for Windows printout); Tab 180, AWP038-0705 (April 2002 Red Book for Windows printout); Tab 189, AWP039-2444 (April 2000 Red Book for Windows printout).)

United States' Response: The United States disputes that "few" hard copy printouts from the quarterly CD-ROM updates were produced. Further answering, an employee at one DMERC had a practice of printing out pages from the quarterly CD-ROM Red Book updates whenever there were changes in the reported prices. (Fauci Exhibit 167 (8/27/2008 Eiler Dep.), at 293:17 - 295:11) Such hard copy printouts have been produced to Roxane on CDs labeled AWPCD001, AWPCD002 and AWQ065. The United States does dispute that the printouts produced by the DMERCs list all drugs by their full label name. For example, Roxane's NovaPlus ipratropium bromide product was listed at "IPRATROPIUM BROMIDE - NOVAPLUS." Tab 180. Other hard copy printouts listing products with "NovaPlus" in the product name are found at Fauci Exhibit 171.

213. Although the internal procedures required the DMERCs to consult manufacturers, the Physicians Desk Reference book, or the Red Book itself if questions arose about the classification of a drug, there is no evidence that any DMERC did so with respect to classifying iptratropium bromide products. (Tab 22, 8-26-08 Eiler Dep. 119-20.)

United States' Response: The phrase "internal procedures" is ambiguous as used in this paragraph. The paragraph is otherwise disputed, and it is not supported by the cited authority.

214. The DMERCs did no additional research besides looking at RedBook to determine whether a drug was a generic or a brand. (Tab 24, 9-23-08 Eiler Dep. 559.) The DMERCs did not verify their classifications using First DataBank, Medispan, or any other compendia besides RedBook. (*Id*.)

United States' Response: The United States admits that the DMERCs did not look to First Data

Bank or Medi-Span to "verify their classifications" of products' as brands or generics. The paragraph is otherwise disputed, and is not supported by the cited authority. Further answering, the DMERCs classified products as brands according to criteria published in the Federal Register; i.e., based on whether the products had label names other than the generic chemical name of the drug. (Fauci Exhibit 163 (Stone Decl.), ¶¶ 8-9; Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 29-31; *see also* United States' Response to Paragraph 180)

215. First Data Bank is a widely-used pricing compendium relied on by commercial and government third-party payors, including many State Medicaid programs, as well as others in the pharmaceutical industry to determine the generic status of NDCs. (Tab 182, Aff. of F. Scott Morton ¶ 7.)

United States' Response: Disputed. The phrase "to determine the generic status of NDCs" is ambiguous as used in this paragraph. Further answering, Roxane offers no evidence to support a finding that State Medicaid programs or the Medicare program relied on or even looked to First Data Bank to classify products as brands or generics.

216. In order to assist these entities in determining whether a drug is a generic or brand, First Data Bank publishes a database containing several different "classification indicators." (Tab 182, Aff. of F. Scott Morton ¶ 3.)

United States' Response: The phrase "these entities" is ambiguous as used in this paragraph. The paragraph is disputed to the extent it suggests that State Medicaid programs relied on First Data Bank in classifying products as brands or generics. (*See supra* United States' Response to Paragraph 215) The United States does not dispute that First Data Bank published a database with six "classification indicators."

217. Among others, these indicators include the "generic name drug indicator" and the "generic price indicator." (Tab 182, Aff. of F. Scott Morton ¶ 3.)

United States' Response: Undisputed.

218. During the relevant time period, all of First DataBank's classification indicators were ***identical*** for Roxane-label and NovaPlus label ipratropium bromide. (Tab 182, Aff. of F. Scott Morton ¶ 6.)

United States' Response: The United States does not dispute that First Data Bank's "classification indicators" were the same for the "Roxane-label" ipratropium bromide products and Roxane's NovaPlus ipratropium bromide products. The United States disputes the materiality of this paragraph to the issue of whether the DMERCs properly classified NovaPlus ipratropium bromide as a brand, as that classification was made pursuant to criteria published in the Federal Register and there is no evidence the DMERCs relied on or even looked to First Data Bank in classifying drugs as brands or generics. (*See supra* United States' Response to Paragraph 180)

219. For example, under "generic name indicator," First DataBank listed ***both*** the Roxane-label and NovaPlus-label ipratropium bromide as "Generically named AND multiple source." (Tab 182, Aff. of F. Scott Morton ¶¶ 5-6.)

United States' Response: The United States does not dispute that First Data Bank's "generic name indicator" listed the "Roxane-label" ipratropium bromide and NovaPlus ipratropium bromide as "Generically named and multiple source." The United States disputes the materiality of this paragraph to the issue of whether the DMERCs properly classified Roxane's NovaPlus ipratropium bromide products as a brand, as that classification was made pursuant to criteria published in the Federal Register and there is no evidence the DMERCs relied on or even looked to First Data Bank in classifying drugs as brands or generics. (*See supra* United States' Response to Paragraph 180)

220. Similarly, under "generic price indicator," First DataBank listed ***both*** the Roxane-label and NovaPlus-label ipratropium bromide as "Priced as a lower cost alternative." (Tab 182, Aff. of F. Scott Morton ¶¶ 5-6.)

United States' Response: The United States does not dispute that First Data Bank's "generic price indicator" listed the "Roxane-label" and NovaPlus ipratropium bromide as "Priced as a lower cost alternative." The United States disputes the materiality of this paragraph to the issue of whether the DMERCs properly classified Roxane's NovaPlus ipratropium bromide products as a brand, as that classification was made pursuant to criteria published in the Federal Register and there is no evidence the DMERCs relied on or even looked to First Data Bank in classifying drugs as brands or generics. (*See supra* United States' Response to Paragraph 180)

F. Some Of The DMERCs Inconsistently Classified The Roxane And NovaPlus-Label Ipratropium Bromide Products As Both Brands And Generics, At Differing Times.

221. The four DMERCs varied considerably in their classifications of the NovaPlus and Roxane label ipratropium bromide products. (Tab 18, 3-5-09 Duggan Dep. 146). Of the four DMERCs, only DMERC-A consistently placed the NovaPlus and Roxane labeled products in its generic arrays throughout the pertinent time period. (Tab 183, Ex. A to Decl. of C. King at AWQ071-0043, AWQ071-0047, AWQ071-0052, AWQ071-0059, AWQ071-0063, AWQ071-0066, AWQ071-0070, AWQ071-0073, AWQ071-0077 (DMERC-A arrays).) The remaining three DMERCs classified either the NovaPlus label product or the Roxane label as a brand, and, in some instances, alternated the classification of the *same* product across time periods. (*See, e.g.*, Tab 24, 9-23-08 Eiler Dep. 549, 552-554; Tab 184, Eiler U.S. Ex. 11 (AdminaStar Federal Arrays) at AWP038-0704-05; Tab 185, Roxane 118 at AWP033-1352.)

United States' Response: The phrase "varied considerably" is ambiguous as used in this paragraph. The United States admits that DMERC-A consistently, but incorrectly, treated Roxane's NovaPlus ipratropium bromide product as a generic. The United States also admits that DMERC-A consistently, and correctly, treated the "Roxane-label" ipratropium bromide product as a generic. The paragraph is otherwise disputed, and is not supported by the cited authority. Further answering, the evidence establishes that the CIGNA and AdminaStar DMERCs treated NovaPlus ipratropium bromide as a brand for all time periods. (*See infra* United States' Response to Paragraph 224) Further, the CIGNA and the Palmetto DMERCs

treated other products with "NovaPlus" in the product name as brands. (Henderson Common Exhibit 3 (Helton Decl.), ¶ 30; Fauci Exhibit 163 (Stone Decl.), ¶ 9) The Palmetto DMERC treated NovaPlus ipratropium bromide as a brand for all time periods, except that it is not clear whether Palmetto treated NovaPlus ipratropium bromide as a brand or generic from April 2003 to July 2003. (*See infra* United States' Response to Paragraph 222)

222. The Palmetto DMERC placed the NovaPlus product in its generic arrays from April to July 2003, even though it had previously classified the product as a brand in prior arrays. (Tab 186, Roxane Ex. 46 at AWQ022-0074-AWQ-022-077.) Beginning in July 2003, Palmetto re-classified the NovaPlus product as a brand and placed it back into its brand array. (Tab 186, Roxane Ex. 46 at AWQ022-0078- AWQ -022-081.)

United States' Response: Disputed. Roxane offers no evidence to support a finding that the Palmetto DMERC arrays classified NovaPlus ipratropium bromide as a generic from April to July 2003. Further answering, the Palmetto DMERC consistently classified NovaPlus ipratropium bromide as a brand from the first quarter of 2001 (when the product first appeared in the Palmetto DMERC's arrays) until the fourth quarter of 2003, except that for one array for the second quarter of 2003 (April 2003 to July 2003), it is not clear how the product was classified. (Fauci Exhibit 163 (Stone Decl.), ¶ 6) For that quarter, the Palmetto array for the relevant HCPCS code does not contain the column (usually entitled "brand") that specifies whether the product was treated in the calculation as a brand or a generic. (*Id.,* ¶¶ 12-14) As a result, it is not certain how the Palmetto DMERC classified NovaPlus ipratropium bromide during the second quarter of 2003. (*Id.*) However, the fact that the product was consistently treated as a brand before the second quarter of 2003 suggests it was likely treated as brand for that quarter as well. (*Id.*) As it is uncertain whether NovaPlus ipratropium bromide was treated as a brand or a generic for the second quarter of 2003, the United States' damages expert (Dr. Duggan) has taken

the approach favorable to Roxane and assumed it was treated as a generic.

223. The AdminaStar Federal DMERC classified the ***Roxane label*** ipratropium bromide as a brand for over one year, from July 2002 to October 2003, even though AdminaStar had previously classified it as a generic for the prior six years. (Tab 24, 9-23-08 Eiler Dep. 552-54; Roxane 118 at AWP033-1352, AWP033-1243, AWP033-1810, AWP033-1653-54, AWP033-2124, AWP033-1988; Tab 184, U.S. Eiler Ex. 11 (AdminaStar Federal arrays).)

United States' Response: Undisputed. Further answering, the United States' expert, Dr. Duggan, corrected this in his damages calculations, and moved the "Roxane-label" ipratropium bromide into the generic side of the arrays from July 2002 to October 2003, thus reducing the calculated damages attributable to Roxane. (Tab 166, at 110 n.82)

224. Both the CIGNA and AdminaStar DMERCs classified the NovaPlus label product as brand in all of the pricing arrays that listed the drug. (Tab 187, Roxane 58 (CIGNA arrays); Tab 185, Roxane 118 at AWP033-0434-35, AWP033-0372-73, AWP033-0268-69, AWP033-1128-29, AWP033-0987-88, AWP033-0862, AWP034-1742, AWP033-0737-38, AWP033-0550-51, AWP033-1474, AWP033-1352, AWP033-1243, AWP033-1810, AWP033-1653-54, AWP033-2124, AWP033-1988 (AdminaStar Federal arrays).)

United States' Response: Undisputed.

G. The Government's Damages Expert Includes Damages Based On The DMERCs' Classification Of NovaPlus As A Brand

225. The Government's damages expert, Dr. Duggan attempted to determine the Government's damages by calculating the "difference" between (1) what the federal government reimbursed for Roxane's NDCs under Medicare and Medicaid from 1996 to 2008 and (2) what the federal government would have reimbursed during the same period if instead Dr. Duggan's average sales prices (derived from Roxane's indirect transactional data) had been used to determine the "actual" AWPs for Roxane's drugs. (Tab 18, 3-5-09 Duggan Dep. 61-64; Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 1.)

United States' Response: Undisputed, except that Dr. Duggan did not "attempt" to determine the United States' damages; he *did* determine the damages. Further answering, Dr. Duggan calculated damages to the Medicare program through 2003.

226. Dr. Duggan's primary methodology consisted of replacing the published AWPs for Roxane's NDCs with his derived AWPs. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report at

11.) He then placed the derived AWPs into electronic pricing arrays prepared based on the original DMERC arrays. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 98-99.)

United States' Response: The phrase "primary methodology" is ambiguous as used in this paragraph. The United States does not dispute that Dr. Duggan calculated damages to the Medicare program for the ipratropium bromide HCPCS codes by replacing Roxane's reported AWPs in the DMERCs' pricing arrays with alternative AWPs (calculated as 125 percent of the average net indirect sales price to the retail pharmacy class of trade), and quantifying the difference in reimbursement.

Dr. Duggan calculated damages to the Medicare program for ipratropium bromide under four scenarios:

- First, Dr. Duggan calculates damages by replacing the AWPs for Roxane's ipratropium bromide products (NDCs 00054-8402-11, 00054-8402-13, and 00054-8402-21) *and* for Roxane's NovaPlus ipratropium bromide products (NDCs 00054-8404-11, 00054-8404-13, and 00054-8404-21) (Tab 166, at 3) ("scenario one," or the "Roxane-Only, NovaPlus" scenario)

- Second, Dr. Duggan calculates damages by replacing only the AWPs for Roxane's ipratropium bromide products, and ignoring Roxane's NovaPlus ipratropium bromide products (*Id.*) ("scenario two," or the "Roxane-Only, No-NovaPlus" scenario)

- Third, Dr. Duggan calculates damages by replacing the AWPs for Roxane's ipratropium bromide products and NovaPlus ipratropium bromide products, as well as the AWPs for Dey's ipratropium bromide products (*Id.,* at 3-4) ("scenario three," or the "Roxane/Dey, NovaPlus" scenario)

- Fourth, Dr. Duggan calculates damages by replacing the AWPs for Roxane's ipratropium bromide products (ignoring Roxane's NovaPlus ipratropium bromide products), and also replacing the AWPs for Dey's ipratropium bromide products (*Id.*, p. 4) ("scenario four" or the "Roxane/Dey, No-NovaPlus" scenario)

With regard to the scenarios three and four, the Roxane and Dey NDCs for ipratropium bromide appear together in the DMERCs pricing arrays. Because the Medicare-allowed reimbursement

amount often was set in reference to the median of the generic AWPs, the submission of inflated AWPs by multiple manufacturers had a joint impact on the allowed amount; that is, Roxane and Dey's reported AWPs combined to shift the median AWP and, therefore, jointly caused a single harm to the Medicare Program. (*Id.*, at 14, 124-25; *see also* Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 39-40)

227. In calculating what the federal government would have reimbursed under Medicare for ipratropium bromide, Duggan used the DMERCs' arrays without studying or attempting to check the DMERCs' prices against the compendia, correcting for inconsistencies, or scrutinizing the DMERCs' process for creating the pricing arrays. (Tab 18, 3-5-09 Duggan Dep. 132-34, 146-49, 152, 166.)

United States' Response: Disputed. Dr. Duggan, through support provided by Myers and Stauffer, LLC, checked the Red Book in certain instances to confirm NDC numbers, and checked certain of the DMERCs' calculations. This is demonstrated in the notes to the electronically re-created arrays prepared by Myers and Stauffer, which have been produced to Roxane. Further, in response to points raised by one of Dey's experts (Dr. David Bradford), Dr. Duggan corrected mathematical errors made in two DMERC arrays and has made minor corresponding adjustments to his Medicare damages calculations. Dr. Duggan will provide a supplement to his reports in the Dey and Roxane cases in the near future.

228. Dr. Duggan presented four independent damages models. (Tab 18, 3-5-09 Duggan Dep. 61-64.) One model calculated damages based on replacing prices for only the Roxane label ipratropium bromide and excluding the NovaPlus label ipratropium bromide products. (referred hereinafter as the "No-NovaPlus model") (Tab 18, 3-5-09 Duggan Dep. 61-64; Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 3B.). A second model replaced prices for both the Roxane label and NovaPlus label ipratropium bromide NDCs. (hereinafter the "NovaPlus model") (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 3A; Tab 18, 3-5-09 Duggan Dep. 61-64.) The last two models calculated damages based on changing prices for Dey ipratropium bromide products in addition to the Roxane drugs. (Tab 18, 3-5-09 Duggan Dep. 61-64.)

United States' Response: Undisputed. (*See supra* United States' Response to Paragraph 226)

229. In the No-NovaPlus model, Dr. Duggan replaced Roxane's AWPs in the arrays with a "revised AWP" to determine whether Medicare spending would be affected. (Tab 18, 3-5-09 Duggan Dep. 140-41; Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 98-99.) Dr. Duggan calculated damages whenever replacing Roxane's prices affected the median of the generic array. (Tab 18, 3-5-09 Duggan Dep. 140-41.)

United States' Response: The phrase "Roxane's AWPs" is ambiguous. The United States does not dispute that in one damages model (the Roxane-Only, No-NovaPlus scenario described *supra* as "scenario two" in the United States' Response to Paragraph 226), Dr. Duggan calculates damages by replacing Roxane's reported AWPs for the Roxane-label ipratropium bromide products with alternative AWPs. Dr. Duggan calculated damages when the alternative AWPs decreased the median AWP (and thereby decreased Medicare's allowed reimbursement amount).

230. Dr. Duggan evaluated the electronic pricing array and lined up the prices. (Tab 18, 3-5-09 Duggan Dep. 131-32.) If there was an odd number of prices, he determined the median by disregarding the highest and lowest prices and taking the middle price. (Tab 18, 3-5-09 Duggan Dep. 131-32.) If there was an even number of prices, Dr. Duggan disregarded the highest and lowest prices and averaged the middle two prices. (Tab 18, 3-5-09 Duggan Dep. 131-32.)

United States' Response: Disputed, inasmuch as Dr. Duggan did not independently determine the medians, but rather replicated the calculations that were done by the DMERCs (except in one instance where a mathematical error was encountered, and Dr. Duggan corrected the error in favor of Roxane). Further, Dr. Duggan did not "disregard" the highest and lowest prices; instead, the DMERCs and Dr. Duggan considered all prices included in the array used to determine the median generic AWP. The method used by the DMERCs is described in detail in the Declaration of Carolyn Helton, which is Exhibit 3 to the Henderson Common Declaration.

231. Under the No-NovaPlus model, substituting Roxane's revised AWPs has no effect on the median later on in the relevant period for most of the DMERCs. (Tab 20, 5-18-09 Duggan, Dep. 184.)

United States' Response: Disputed. The phrase "has no effect on the median later on in the

relevant period for most of the DMERCs" is ambiguous. Further answering, the allowed amounts for Medicare claims processed by the CIGNA DMERC would have been lower from the second quarter of 1997 through the third quarter of 2001 if Roxane's reported AWPs for its ipratropium bromide products (the 8402 products) had been reduced by one percent or more. (Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 22, 24) For periods after the third quarter of 2001, the Medicare-allowed amount for claims processed by CIGNA would have been lower if the AWPs for both the Dey and Roxane ipratropium products had been reduced by one percent or more. (*Id.*, ¶¶ 39-41)

232. For example, in the No-NovaPlus model, Dr. Duggan explained that the Palmetto DMERC's allowed amount was unaffected after the third quarter of 2001 when replacing Roxane's published AWPs with his derived AWPs. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 104; Tab 188, D. Williams Aff. at ¶ 11.)

United States' Response: Undisputed, to the extent this paragraph is discussing the "Roxane-Only, No-NovaPlus" model described *supra* as scenario two in the United States' Response to Paragraph 226.

233. Similarly, under Dr. Duggan's analysis, replacing Roxane's AWP with a revised AWP did not affect the median of the DMERC-A arrays after the third quarter of 2001. (Tab 188, D. Williams Aff. at ¶ 11.)

United States' Response: Undisputed, to the extent this paragraph is discussing the "Roxane-Only, No-NovaPlus" model, described *supra* as "scenario two" in the United States' Response to Paragraph 226.

234. Under Dr. Duggan's analysis, replacing Roxane's AWP with a revised AWP also did not affect the median of the CIGNA arrays after the third quarter of 2001. (*Id.*)

United States' Response: Undisputed, to the extent this paragraph is discussing the "Roxane-Only, No-NovaPlus" model, described *supra* as "scenario two" in the United States' Response to

Paragraph 226.

235. And under Dr. Duggan's analysis, replacing Roxane's AWP with a revised AWP did not affect the median of the AdminaStar arrays after the second quarter of 2000. (*Id*. at 10.)

United States' Response: Undisputed, to the extent this paragraph is discussing the "Roxane-Only, No-NovaPlus" model, described *supra* as "scenario two" in the United States' Response to Paragraph 226.

236. Under the No-NovaPlus model, Duggan attempted to correct or reconcile some of the DMERCs errors based on "what [he] considered to be most appropriate at the time." (Tab 18, 3-5-09 Duggan Dep. 137-38.) For example, Duggan decided to correct AdminaStar's erroneous inclusion of the Roxane-label ipratropium bromide in the branded portion of the array. (Tab 18, 3-5-09 Duggan Dep. 138-41, 144-45.)

United States' Response: Undisputed to the extent this paragraph applies to the Roxane-label ipratropium bromide products (the 8402 products) for the 2002Q3 to 2003Q3 period; except, however, Dr. Duggan did not "attempt" to make the correction described in the example. He did make the correction.

237. Under the NovaPlus model, Duggan replaced prices for both the Roxane label and NovaPlus-label AWPs. (Tab 18, 3-5-09 Duggan Dep. 62-63.) Dr. Duggan then calculated damages whenever replacing Roxane's prices would have affected the median of the generic array or the lowest brand price because, in his view, movement in either one would affect the allowed amount. (Tab 18, 3-5-09 Duggan Dep. 140-41.)

United States' Response: The United States disputes the phrase "in his view" to the extent it suggests there are circumstances where lowering either the median generic AWP or the brand AWP would not affect Medicare's allowed amount. The paragraph is otherwise admitted, inasmuch as it discusses the "Roxane only, NovaPlus included" damages model, described *supra* as "scenario one" in the United States' Response to Paragraph 226.

238. With respect to the NovaPlus label ipratropium bromide, Duggan did not attempt to determine whether the DMERCs' classification of the drug was appropriate and instead "accepted what [the DMERCs] did," relying on each DMERCs' separate determination of

whether the drug was a brand or generic without correcting for any errors or inconsistencies. (Tab 18, 3-5-09 Duggan Dep. 145-47; Tab 20, 5-18-09 Duggan Dep. 159.)

United States' Response: Disputed. (*See supra* Paragraph 236 (where Roxane agrees that Dr. Duggan corrected AdminaStar's erroneous classification of Roxane's ipratropium bromide products (the 8402 products) as brands)) Otherwise, the United States admits that Dr. Duggan did not second-guess the DMERCs' determinations regarding the appropriate classification of Roxane's NovaPlus ipratropium bromide.

239. Thus, because the DMERCs' treatment varied across DMERCs and for certain time periods within DMERCs, Duggan sometimes treated the NovaPlus label as a brand as the DMERCs did under the NovaPlus model. (Tab 18, 3-5-09 Duggan Dep. 146, 152-53.)

United States' Response: The United States disputes Roxane's characterization of Dr. Duggan's analysis. As stated *supra*, Dr. Duggan's model corrected certain AdminaStar arrays that erroneously treated Roxane's ipratropium bromide products (the 8402 products) as brands and, in addition, Dr. Duggan assumed (to Roxane's advantage) that the Palmetto array for the second quarter of 2003 treated the NovaPlus products as generics, even though Palmetto may not have done that. (*See supra* United States' Response to Paragraph 222)

240. Because the regulations allowed payments to be based on "the lowest brand AWP" whenever it was lower than the median of generic AWPs, in Dr. Duggan's "but-for" world, the "revised NovaPlus AWP" now becomes the hypothetical "lowest brand AWP." (Tab 18, 3-5-09 Duggan Dep. 140-141, 159-60.)

United States' Response: The United States does not dispute that from November 1998, regulations required Medicare to reimburse for multi-source drugs based on the lesser of the median generic AWP or the lowest AWP of the brand name forms of the drug (63 Fed. Reg. 58,814, 58,905 (Nov. 2, 1998)). Therefore, when Dr. Duggan replaces the NovaPlus ipratropium bromide AWPs with alternative AWPs, the alternative AWPs became the "lowest brand AWP"

in those instances where the DMERCs properly classified NovaPlus ipratropium bromide as a brand.

241. As a result, the NovaPlus prices establish the payment basis for *all* quarters and *all* ipratropium bromide claims. (Tab 18, 3-5-09 Duggan Dep. 140-141, 159-60.)

United States' Response: The United States does not dispute that Dr. Duggan's alternative AWPs for NovaPlus iprtraopium bromide establish the basis of payment for ipratropium bromide for those quarters when NovaPlus ipratropium bromide products were classified as brands.

242. Although the misclassification of NovaPlus as brand had no impact upon Medicare payments in the real world (because the NovaPlus and Roxane label AWPs were identical at all times), under Dr. Duggan's "but for" world, it has a massive impact. (Tab 20, 5-18-09 Duggan Dep. 158.) During any quarter in which Dr. Duggan finds liability in the NovaPlus model, he assigns *all* J-Code payments to Roxane, which include claims for payments for not only Roxane products, but any claims submitted for other manufacturers' ipratropium products. (Tab 20, 5-18-09 Duggan Dep. 157-58.)

United States' Response: The United States disputes that NovaPlus was misclassified (except where DMERCs treated it as a generic). (*See supra* United States' Responses to Paragraphs 141-42, 174-76, 180-85) The United States disputes any suggestion that Roxane's false pricing had no impact on Medicare payments. On the contrary, Roxane's reporting of false prices for its ipratropium bromide products – both the generic Roxane-label products and the NovaPlus brand products – had very substantial impacts on Medicare payments. The United States admits when NovaPlus ipratropium bromide was classified as a brand, replacing its AWPs lowers the reimbursement for all Medicare claims for ipratropium bromide.

243. There is a significant difference in Duggan's calculation of alleged damages under No-NovaPlus model (*i.e.*, excluding NovaPlus label products) and NovaPlus models (*i.e.,*incorporating both the Roxane label and NovaPlus label); specifically, Dr. Duggan calculates an alleged damage figure of $234 million for his No-NovaPlus Model but $1.17 billion under the model that includes the NovaPlus label product. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 3; Tab 18, 3-5-09 Duggan Dep. 183.)

United States' Response: Undisputed, to the extent this paragraph is referring to the Roxane-Only, NovaPlus model and the Roxane-Only, No-NovaPlus model.

244. Dr. Duggan later conceded that the No-NovaPlus scenario recognizes that NovaPlus had "virtually no utilization" despite its "massive effect" on his damages calculations. (Tab 20, 5-18-09 Duggan Dep. 155-56.) He testified that he understands that there are good arguments that NovaPlus is not a brand drug and remains "agnostic" as to whether the NovaPlus or No-NovaPlus damages model is more appropriate. (Tab 18, 3-5-09 Duggan Dep. 181-82; Tab 20, 5-18-09 Duggan Dep. 155-56, 169.) He testified that one could make a good case for the No-NovaPlus scenario based on the fact that the DMERCs may have misclassified NovaPlus as a brand, the very low utilization of the NovaPlus products under Medicare Part B and Roxane's declining marketshare during the time period when Dr. Duggan calculates damages purportedly attributable to the NovaPlus prices. (Tab 20, 5-18-09 Duggan Dep. 157-60.)

United States' Response: The United States admits that Dr. Duggan, as an economist, does not offer an opinion as to whether the DMERCs correctly classified NovaPlus ipratropium bromide as a brand product. Accordingly, Dr. Duggan calculated damages models including NovaPlus ipratropium bromide, and excluding NovaPlus ipratropium bromide. In the damages models which include NovaPlus ipratropium bromide, Dr. Duggan treats NovaPlus ipratropium bromide as it was treated by the DMERCs. The United States also does not dispute that Medicare reimbursed only a small number of claims for NovaPlus ipratropium bromide. The paragraph is otherwise denied, and is not supported by the cited authority.

H. The Government's Damages Are Also Inflated By Their Expert's Failure To Discount Damages As A Result of Three DMERCs Failure To Include NDCs For A Generic Product In Their Arrays.

245. Two ipratropium bromide inhalation solution products manufactured by Zenith Goldline appeared in the April 2000 monthly Red Book paper update and in the April 2000 electronic Red Book for Windows publication. (Tab 178, April 2000 RedBook Update at 43; Tab 189, AWP039-2444 (April 2000 Red Book CD Printout).).

United States' Response: Undisputed. Further answering, the Zenith Goldline products were listed in the Red Book as follows: "(Zenith Goldline) SOL,IH (VIAL, P.F.) (U.D.) (Tab 178, at

43) The designation "P.F." means "Preservative Free." (Fauci Exhibit 163 (Stone Decl.), ¶¶ 16-17)

246. One of these Zenith Goldline ipratropium bromide products (NDC 00172-6407-44) had an AWP of $44.10. CD Printout; Tab 189, AWP039-2444 (April 2000 RedBook CD Printout).) The second Zenith Goldline ipratropium bromide product (NDC 00172-6407-49) had an AWP of $105.60 price listed in CD printout. (Tab 178, April 2000 RedBook at 43; Tab 189, AWP039-44 (April 2000 Red Book CD Printout).)

United States' Response: Undisputed.

247. AdminaStar Federal included these two Zenith Goldline NDCs on a non-final array for the second quarter of 2000. (Tab 185, Roxane Ex. 118 at AWP033-45 (AdminaStar Federal arrays).) It is unclear whether AdminaStar Federal decided to use that array to calculate the maximum allowable cost for that quarter. (Tab 23, 8-27-08 Eiler Dep. 297-301.)

United States' Response: Disputed. One Zenith Goldline product appears in the array AdminaStar Federal used to calculate the allowable amount for this quarter. This array has been produced to Roxane.

Further answering, the inclusion of the Zenith Goldline product in the array appears to have be in error. As noted *supra*, the Zenith Goldline products were labeled "Preservative Free." (Fauci Exhibit 163 (Stone Decl.), ¶¶ 16-17) Preservative Free products often contained special packaging and increased pricing. (*Id.*) The DMERCs – including AdminaStar Federal – generally did not include such products in their pricing arrays because they were regarded as convenience items. (*Id.*; Fauci Exhibit 167 (8/27/2008 Cheryl Eiler Dep.), at 289:22 - 291:5 (wherein Ms. Eiler testified that pursuant to CMS instruction AdminaStar Federal generally did not include preservative free products in pricing arrays); Fauci Exhibit 165 (8/26/2008 Cheryl Eiler Dep.), at 147:9 - 148:16) The (apparently erroneous) inclusion of the Zenith Goldline product in the AdminaStar Federal arrays benefitted Roxane, as seen in Paragraphs 249-50 *infra*.

248. From the third quarter of 2000 through the second quarter of 2002, AdminaStar

added the Zenith Goldline drugs to the generic portion of the pricing arrays it used for ipratropium bromide. (*See* Tab 185, Roxane Ex. 118 at AWP033-72–AWP033-73, AWP033-0268-69, AWP033-1128–29, AWP033-0987–88, AWP033-0862, AWP033-1742, AWP033-0737–738, AWP033-055051, AWP033-1474 (AdminaStar Federal arrays).)

United States' Response: Undisputed. (*See infra* United States' Response to Paragraph 247)

249. The Government's damages expert, Dr. Duggan, found that once these values were added to AdminaStar's arrays, the AWPs for Roxane's drugs no longer affected the calculation of the median AWP for the J7644 J-Code. (Tab 188, D. Williams Aff. ¶ 13.)

United States' Response: Undisputed, to the extent this paragraph refers to the Roxane-Only, No-NovaPlus scenario described *supra* as "scenario two" in the United States' Response to Paragraph 226. Dr. Duggan calculates damages for later quarter when considering the joint impact Roxane and Dey's price reporting had on Medicare.

250. After the second quarter of 2000, Dr. Duggan's methodology properly dictates that there should be no damages for Roxane from that time onward. (*Id*.)

United States' Response: The United States does not dispute that in the Roxane-Only, No-NovaPlus scenario, Dr. Duggan stopped calculating damages after the second quarter of 2000 for AdminaStar Federal because the AWPs for Roxane's ipratropium bromide products (the 8402 products) no longer affected the median generic AWP. As noted *supra*, the (apparently erroneous) inclusion of the Zenith Goldline products in the AdminaStar arrays benefits Roxane.

For periods after the second quarter of 2000, Dr. Duggan calculates the damages when considering the joint impact Roxane and Dey's price reporting had on Medicare.

251. Unlike AdminaStar Federal, the other three DMERCs did not include the Zenith Goldline ipratropium bromide products in any of their pricing arrays. (*See* Tab 186, Roxane Ex. 46 (Palmetto arrays); Tab 187, Helton Ex. 58 (CIGNA arrays); Tab 152, Ex. A to Decl. of C. King (DMERC-A arrays).)

United States' Response: Undisputed. (*See infra* United States' Response to Paragraph 252)

As noted *supra*, the Zenith Goldline products were labeled "Preservative Free," (Fauci Exhibit

163 (Stone Decl.), ¶¶ 16-17), and were properly excluded from pricing arrays by the other three DMERCs. (*Id.*; Fauci Exhibit 167 (8/27/2008 Cheryl Eiler Dep.), at 289:22 - 291:5; Fauci Exhibit 165 (8/26/2008 Cheryl Eiler Dep.), at 147:9 - 148:16)

252. As a result, the Government's damages expert, Dr. Duggan calculated damages for DMERC-A, Palmetto, and CIGNA after the second quarter of 2000. (Tab 188, D. Williams Aff. ¶ 14.) Dr. Duggan calculates damages for these quarters totaling $87.99 million. (*Id.*)

United States' Response: The United States does not dispute that Dr. Duggan calculated damages for DMERC-A, Palmetto and CIGNA after the second quarter of 2000. The United States disputes any suggestion that Dr. Duggan should not have done so because the decision to exclude the Zenith Goldline product was proper and pursuant to the DMERCs' policy. (Fauci Exhibit 163 (Stone Decl.), ¶¶ 16-17; Fauci Exhibit 167 (8/27/2008 Cheryl Eiler Dep.), at 289:22 - 291:5; Fauci Exhibit 165 (8/26/2008 Cheryl Eiler Dep.), at 147:9 - 148:16)

In addition, (a) minor differences in the mechanics of pricing determinations were foreseeable; (b) Roxane was never misled into thinking the DMERCs made pricing determinations with perfect consistency; (c) Roxane never relied on any belief or assumption about the uniformity of DMERC calculations in reporting AWPs; and (d) there was no law or CMS instruction that required or expected perfect uniformity in the DMERCs' quarterly pricing determinations. Further answering, Dr. Duggan also calculated damages after the second quarter of 2000 based on the joint harm to the Medicare program caused by Roxane and Dey's price reporting.

XVIII. DIVESTMENT OF ORAMORPH SR, ROXANOL & ROXICODONE

253. On September 28, 2001, Roxane divested certain drugs to Elan Pharma International Ltd. ("Elan"), including all Oramorph SR (0054-4793-25, 0054-4805-27, 0054-4790-25, 0054-4805-25, 0054-4805-19, 0054-4792-25), Roxanol (0054-3751-58, 0054-3751-50, 0054-3751-44), and Roxicodone (0054-4658-25, 0054-4665-25) NDCs at issue in this Action. (Tab 190,

Asset Purchase Agreement ¶ 1.1 at 8-9; U.S. Compl. Ex A (noting that Roxane divested each of these NDCs to Elan)

United States' Response: Undisputed.

254. After the divestment, Elan owned all of the NDAs associated with these NDCs and assumed all liabilities and obligations arising from the manufacture, sale, and marketing of these products. (Tab 190, Asset Purchase Agreement ¶ 1.1 at 2, ¶ 2.1(d) at 11)

United States' Response: Undisputed.

XIX. THE GOVERNMENT HAS NO EVIDENCE SUPPORTING ITS UNJUST ENRICHMENT OR AZATHIOPRINE MEDICARE CLAIMS.

255. In response to a Roxane interrogatory served October 1, 2008 asking for evidence supporting the unjust enrichment claim, the Government stated the following:

> Through reporting inflated prices, Roxane ensured that its customers received inflated reimbursement from Medicare and Medicaid. Roxane then knowingly promoted "spreads" between its fraudulently inflated prices and its actual sales prices as an inducement to its customers.

(Tab 191, U.S. Objs. & Resps. to Roxane's 1st Set of Interrogs. at 55)

United States' Response: Undisputed.

256. Roxane's ipratropium bromide sales decreased during the time period when the Government's purported "spreads" were growing dramatically. (Tab 69, D. Williams Dep. 577-78; Tab 192, 3-13-09 Expert Report of Darrell L. Williams at 12)

United States' Response: The United States does not dispute that Roxane's market share for ipratropium bromide decreased generally over time. The paragraph is otherwise denied and is not supported by the cited authority.

257. In addition, the Government's damages expert failed to conduct any Medicare-specific analyses or render Medicare-specific opinions with respect to azathioprine. (Tab 18, 3-5-09 Duggan Dep. 74)

United States' Response: Undisputed.

XX. THE GOVERNMENT'S METHODOLOGY OF ALLEGED MEDICAID DAMAGES.

A. Overview Of The Government's Methodology For Calculating Alleged Medicaid Damages.

258. The Government's expert, Dr. Mark G. Duggan, utilizes data from a variety of sources to determine the amounts by which federal-State Medicaid program spending purportedly would have changed if the alternative prices that he calculates, *i.e.*, "revised" Average Wholesale Prices ("Revised AWPs") and Wholesaler Acquisition Costs ("Revised WACs"), had been used as a basis of payment. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 9).

United States' Response: Dr. Duggan's report (Tab 166) does not refer to the alternate AWPs and WACs he calculates as "revised." The United States does not dispute that Dr. Duggan utilized data from several sources in calculating damages for the Medicaid program. Specifically, Dr. Duggan used claims data collected directly from state Medicaid agencies as well as sources of data collected by CMS from state Medicaid agencies in connection with CMS' administration of the Medicaid program. (Henderson Common Exhibit 41 (Declaration of Mark Duggan) (hereinafter "Duggan Decl."), ¶ 12) The data collected by CMS includes State Drug Utilization Data ("SDUD") as well three similar types of data known as Medicaid Analytic Extract ("MAX") data, the State Medicaid Research Files ("SMRF") and the Medicaid Statistical Information System ("MSIS") data. (*Id.*) These latter three sets of data are generally referred to as SMRF/MAX or SMRF/MAX/MSIS data. (*Id.*)

259. Dr. Duggan focuses on the 35 NDCs listed in the United States' First Amended Complaint ("Medicaid Subject Drugs"), which relate to nine different drug products: Azathioprine, Diclofenac Sodium, Furosemide, Hydromorphone, ipratropium bromide, Oramorph SR, Roxanol, Roxicodone, and Sodium Polystyrene Sulfonate. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 9; Tab 137, FAC Ex. A.)

United States' Response: The phrase "focuses on" is ambiguous as used in this paragraph. The United States does not dispute that Dr. Duggan calculated Medicaid damages for each of the Subject Drugs, and Medicare damages for ipratropium bromide and NovaPlus ipratropium

bromide.

B. Description Of Datasets Utilized By The Government.

260. When calculating Medicaid damages, Dr. Duggan utilizes five different datasets relating to the Medicaid Subject Drugs. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 25-30, Tables 29 and 31A-B)

United States' Response: The phase "datasets" as used in this paragraph is misleading; Dr. Duggan utilizes multiple datasets comprised of five different types of data. These five different types of data are properly referred to as "dataset types." The United States does not dispute that, to varying degrees, Dr. Duggan utilized state claims data, SDUD data, and SMRF/MAX/MSIS data. (Henderson Common Exhibit 41 (Duggan Decl."), ¶ 12)

261. The first dataset utilized by Dr. Duggan comprises State Medicaid claims data that was produced by the following sixteen State Medicaid programs to the United States (hereinafter, the "State Medicaid Claims Data"): California, Florida, Georgia, Illinois, Kentucky, Louisiana, Massachusetts, Michigan, Missouri, New Jersey, New York, North Carolina, Pennsylvania, Texas, Virginia and Wisconsin. Collectively, these sixteen States are referred to as the "Sixteen State Sample." (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report, Table 29)

United States' Response: The phrase "dataset" is misleading as used in this paragraph; the data produced by the sixteen states referenced in this paragraph constitute sixteen *separate* datasets. The United States does not dispute that Dr. Duggan utilized claims data from the sixteen states programs referenced above in his damages calculations. Further answering, those sixteen states account for 68% of all claims for the Subject Drugs. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 17; Tab 219, at 15) The reason that these states account for such a large share of claims is that Dr. Duggan utilized state claims data for the states with the largest number of claims (including California, Florida and New York), but not for states with the smallest number of claims (such as Vermont, Wyoming or the District of Columbia). (*Id.*)

262. Dr. Duggan has access to Medicaid claims data for an additional fifteen States that

was produced to the United States ("Additional State Medicaid Claims Data"): Alaska, Arkansas, Connecticut, Delaware, Hawaii, Idaho, Iowa, Kansas, Minnesota, Nebraska, New Mexico, Rhode Island, South Carolina, Utah and Wyoming. Dr. Duggan did not use, however, the Additional State Medicaid Claims Data in connection with his calculation of alleged Medicaid damages. (Tab 188, D. Williams Aff. ¶ 2.) The Government failed to obtain and produce State Medicaid Claims Data from the other eighteen State Medicaid programs at issue in this lawsuit.

United States' Response: The United States does not dispute that the fifteen state Medicaid programs referenced above produced claims data to the United States. The United States also received claims data from Ohio. The paragraph is otherwise denied and is not supported by the cited authority. Further answering, Dr. Duggan processed and reviewed the claims data received from all states, and Dr. Duggan utilized this data both to evaluate which states to include in the "Sixteen State Sample" referenced *supra* in Paragraph 261, and to validate the SMRF/MAX/MSIS data. (Henderson Common Exhibit 41 (Duggan Decl.) ¶¶ 17-18)

Further answering, Dr. Duggan utilized claims data from South Carolina to verify his extrapolation of Medicaid damages. Specifically, Dr. Duggan repeated the algorithm he used to calculate damages for the "Sixteen States Sample" for South Carolina, and verified that the damages he calculated in his expert report (based on extrapolation) for South Carolina closely approximated the damages he calculated based on the actual claims data. (Tab 219, at 19) Specifically, the damages calculated based on the extrapolation were $899,000, and the damages Dr. Duggan calculated using the state claims data were $965,000. Further answering, the United States notes that Roxane could have, but chose not to, subpoena additional state claims data.

263. State Medicaid Claims Data and Additional State Medicaid Claims Data vary slightly by States but they typically include the following information for each claim paid by a State Medicaid program: date of service; actual paid amount; NDC; actual billed amount; professional or dispensing fee; copayment amount; third party payment; ingredient cost; provider ID; a field indicating if a State maximum allowable cost ("MAC") or federal upper limit ("FUL") was used to determine the reimbursement amount for the claim, as well as the unit price for that MAC or FUL for each claim; and, data concerning the basis of payment for a particular claim

(*e.g.*, whether a claim was paid on an AWP or WAC). (Tab 188, D. Williams Aff. ¶ 3.)

United States' Response: The United States notes that only a minority of the state claims datasets include fields identifying the basis of payment for a particular claim, or listing unit prices for a MAC or FUL. The United States does not otherwise dispute this paragraph.

264. The second dataset utilized by Dr. Duggan consists of State Medicaid Research Files ("SMRF" data) that was produced by CMS for the time period 1991 through 1998. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 28-30, Tables 29 and 31A-B)

United States' Response: The phrase "dataset" is misleading as used in this paragraph. The paragraph is not otherwise disputed. Further answering, the SMRF/MAX data collectively covered the time period from 1991 through 2004. (Tab 166, at 28-30) The SMF/MAX/MSIS data is claims level data which contains over 40 data elements including, for example, the NDC, the date of service, the charged amount, the paid amount, the date of payment, and the quantity. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 15)

265. The third dataset utilized by Dr. Duggan consists of Medicaid Analytic eXtract General Information ("MAX" data) that was produced by CMS for the time period 1999 through 2004 (collectively, "SMRF-MAX" datasets). (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 28-30, Tables 29 and 31A-B)

United States' Response: The phrase "dataset" is misleading as used in this paragraph. The dataset type referred to in this paragraph called Medicaid Analytic Extract. The paragraph is not otherwise disputed. (*See supra* United States' Response to Paragraph 264)

266. The fourth dataset utilized by Dr. Duggan consists of Medicaid Statistical Information Statistics ("MSIS" data) that was produced by CMS for the time period 1999 through 2005. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 28, n.13)

United States' Response: The phrase "dataset" is misleading as used in this paragraph. The dataset type referred to in this paragraph is called Medicaid Statistical Information System. The paragraph is not otherwise disputed. (*See supra* United States' Response to Paragraph 264)

267. Although the SMRF-MAX and MSIS datasets vary, they each typically include the following information for each claim paid by a State Medicaid program: date of service; paid amount rounded to the nearest dollar; NDC; quantity; billed amount rounded to the nearest dollar; third party payment; and, provider ID. (Tab 188, D. Williams Aff. ¶ 5.) The SMRF-MAX and MSIS datasets, unlike the State Medicaid Claims Data and Additional State Medicaid Claims Data, do ***not*** provide the following information for each claim: the specific amount actually paid on the claim; the specific amount actually billed by the provider; dispensing fee; copayment amount; and, a field indicating whether a claim was paid on a MAC or FUL. (*Id.*) Thus, these datasets do not contain the data required to calculate the basis of payment for a claim. (*Id.*)

United States' Response: The United States disputes that state Medicaid claims data "typically" includes a field indicating whether a claim was paid based on a MAC or an FUL. The phrase "specific amount" is ambiguous as used in the second sentence of this paragraph. The United States disputes the second sentence of this paragraph to the extent it suggests that SMRF/MAX data does not include the amount paid on a claim. The SMRF/MAX data does include such information. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 15) The United States admits that the datasets contained in the SMRF/MAX/MSIS data do not contain the data required to calculate the basis of payment for a claim. The United disputes the materiality of this point, however, because Dr. Duggan's damages calculations account for states' adjudication formulas which overwhelmingly paid claims on the basis of a "lower of" methodology. Therefore, Dr. Duggan's analysis only produced a damages figure in circumstances where alternative AWPs for Roxane's products would have caused a state to reimburse a claim in a lower amount than it otherwise did. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 44)

268. The fifth dataset utilized by Dr. Duggan consists of State Drug Utilization Data ("SDUD") that was produced by CMS for the time period 1991 through 2008. (Tab 166, Duggan Report at 25-28, Tables 29 and 31A-B) SDUD provides only aggregated, or summary, claim information on a State-specific, NDC-quarter level. (*Id.*) SDUD typically includes the following information for each State: NDC-quarter; quantity; total number of units reimbursed by the State Medicaid program; total number of prescriptions for the NDC; and the total dollar amount paid by the State Medicaid Program for that NDC during the given quarter. (Tab 188, D. Williams Aff. ¶ 6.) SDUD does ***not*** include the following information: the specific amount actually paid

on the claim; the specific amount actually billed by the provider; dispensing fee; copayment amount; a field indicating whether claims were paid on a MAC or FUL. (*Id*.) Therefore, SDUD does not contain the data required to calculate the basis of payment for a claim. (*Id*.) Collectively, the SDUD, SMRF-MAX and MSIS datasets are referred to as the "CMS Datasets."

United States' Response: Undisputed, except for the following: the SDUD dataset extends into but not "through" 2008 and the SDUD dataset does not include both "quantity" and "total number of units" fields (one or the other is present, not both). The SDUD dataset differs significantly from the SMRF/MAX/MSIS data, (*see supra* Paragraphs 263 and 268), and referring to these datasets collectively as the "CMS Datasets" is confusing.

C. Dr. Duggan Did Not Determine Whether State Medicaid Programs Complied With Their CMS-Approved Regulatory Formulae When Paying Medicaid Claims.

269. Dr. Duggan did not determine whether CMS approved the Medicaid reimbursement formulas utilized by the State Medicaid Programs in the payment of claims. Duggan testified that "I did not examine whether the adjudication methods were approved by CMS." (*Id.*)

United States' Response: The United States does not dispute that Dr. Duggan did not personally examine whether CMS approved the reimbursement formulas utilized by the various state Medicaid programs. Further answering, Dr. Duggan relied upon the Myers and Stauffer summaries of the state Medicaid programs' reimbursement formulas. Dr. Duggan also performed calculations in his damages analysis to verify that state Medicaid programs in fact applied such formulas; where the formulas also were not applied, Dr. Duggan allowed for such variances in his calculations. (Henderson Common Exhibit 41 (Duggan Decl.), ¶¶ 44-45)

270. State Medicaid programs do not always adhere to their CMS-approved regulatory formulae when paying Medicaid claims. For example, in Florida, an erroneous computer programming change caused the State Medicaid program to unintentionally remove its WAC-based EAC formula from its reimbursement logic. (Tab 67, 5-25-05 Wells Dep. 453-59) In addition, the Hawaii reimbursement system was incorrectly set up "so that the FUL price would override the Hawaii MAC price . . . even if the FUL price was higher." (Tab 16, 4-29-08 Donovan Dep. 186-87;

Tab 193, HHD041-076-077 (Hawaii State Plan); Tab 194, HHD041-072-075; Tab 195, HHC016-342-343; Tab 196, HHD041-0061; Tab 197, HHD041-065) Also, prior to 2003 in Alaska, drugs subject to a FUL were reimbursed only at the lower of the FUL or the billed charge, not the AWP-based EAC, because Alaska's reimbursement methodology "failed to incorporate" the EAC. (Tab 4, 8-21-08 Campana Dep. 240-42; Tab 198, Abbott Ex. 1122)

United States' Response: The United States admits that in rare and immaterial instances, a State Medicaid program has deviated slightly from the CMS-approved methodology. With regard to the second sentence of this paragraph, the United States admits that from July 2000 until April 2002, the Florida Medicaid program inadvertently removed WACs from its reimbursement formula, due to an erroneous computer programming change. This error was corrected in or around April 2002. (Fauci Exhibit 172 (5/25/2004 JerryWells Dep.), at 455:15 - 455:20)

The United States disputes that Hawaii's reimbursement methodology was "incorrect" or that it deviated from Hawaii's approved State Plan. Hawaii regulations provided that FULs would override state MACs, even when the FUL was higher than the MAC. (Fauci Exhibit 173)

The United States admits that prior to 2003 Alaska reimbursed drugs subject to a FUL at the lower of the FUL or the billed charge, and did not incorporate an "AWP-based EAC" into its reimbursement formula. The United States disputes, however, that this was an "error." The described reimbursement methodology was consistent with Alaska's regulations and approved State plan. (Fauci Exhibit 174 (7 AAC § 43.591(c)); Fauci Exhibit 175)

271. Massachusetts paid claims in amounts that exceeded the EAC and the FUL. *Massachusetts v. Mylan Labs.*, No. 03-11865, 2008 WL 5650859, at *4 (D. Mass. Dec. 23, 2008) ("[i]n certain cases, [Massachusetts] reimbursement exceeded the EAC and the FUL.").

United States' Response: Disputed, to the extent Roxane attempts to incorporate findings of fact made in a different case to which the United States was not a party. The United States admits that in certain isolated instances, the Massachusetts Medicaid agency paid reimbursement for individual

claims at amounts above the FUL or the EAC. The United States disputes the materiality of this paragraph to Roxane's liability under FCA, however; the State's failure to pay at a FUL or EAC is only material to the question of damages. *See Massachusetts v. Mylan Labs*, 2008 WL 5650859, at *19 (D. Mass. 2008) Further answering, Dr. Duggan discarded claims paid in amounts that exceeded the billed amounts. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 41)

272. The Office of Inspector General found in its review of reimbursement data from all State Medicaid programs for FY 2001 that some States paid for certain drugs in amounts above the "Federal upper payment limits." (Tab 199, OEI-05-02-00681, Variation In State Medicaid Drug Prices, September 2004, p. iv-v)

United States' Response: The United States does not dispute that in 2004 the Office of Inspector General published a report entitled, *Variations in State Medicaid Prices.* Roxane has correctly, but selectively, quoted excerpts from that report; the entirety of the report referenced is the best evidence of its contents. The United States disputes the relevance of the report to Roxane's liability under the FCA. First, the report does not mention Roxane or refer to any of the Subject Drugs. Second, the report relates to variations in the payment for 28 drugs; the report itself recognizes that one "can't project variations for these 28 drugs to the universe of Medicaid drugs." (Tab 199, at 6)

273. From 1999-2003 Dr. Duggan calculates alleged damages for claims reimbursed by the Massachusetts Medicaid program based on an AWP-based formula. (Tab 188, D. Williams Aff. ¶ 16.)

United States' Response: Disputed. Dr. Duggan's algorithm for calculating damages for Massachusetts consistently applies a transaction-derived WAC, if available. (Tab 166, at 59-60 and n. 45)

274. Similarly, Alabama Medicaid paid for claims using an AWP-based EAC, despite the fact that this payment basis was not authorized in the CMS-approved State Medicaid Plan. (Tab 200, HHD086-010; Tab 201, HHD086-0011-012; Tab 202, ALMED-808004-808005.)

United States' Response: The United States does not dispute that Alabama Medicaid used AWP

to determine its EAC when a WAC price was not available, or that the approved State Plan did not specify the use of AWP when a WAC price was not available. The United States disputes that this is material to Roxane's liability under the FCA, given that the evidence suggests that Roxane intentionally ceased reporting its WACs in order to cause WAC states to use its inflated AWPs. (US-BR-SF ¶¶ 119-136) The United States further notes that Roxane has no standing to complain about any asserted inconsistency between Alabama's reimbursement methodology and the approved State Plan. *See Long Term Care Pharmacy Alliance v. Ferguson*, 362 F.3d 50 (1st Cir. 2004)

D. Dr. Duggan Did Not Determine The Basis Of Payment For Medicaid Claims.

275. Except for New York claims, Dr. Duggan did not determine the payment basis of any of the Medicaid claims at issue. (Tab 19, 3-6-09 Duggan Dep. 289, 290-91) Dr. Duggan also testified that he did not determine whether Roxane AWPs or WACs were in fact used by a particular State Medicaid program. (*Id.* at 300-301)

United States' Response: The United States does not dispute that Dr. Duggan did not set out to determine the precise basis of payment for several million individual Medicaid claims. Such a task was unnecessary because, under the "lower of" methodology used by virtually all states (except Alaska and New York for specific periods of time), if a truthful AWP had resulted in an EAC lower than the original paid amount on the claim, this (a) demonstrates that Roxane caused the Medicaid payment to be higher than it otherwise would have been, and (b) serves as the basis for measuring damages between the amount paid and what would have been paid had the defendant reported a truthful price. (Henderson Common Exhibit 41 (Duggan Decl.) ¶¶ 40-46) Therefore, it is immaterial whether the claim was originally paid based on EAC, U&C, an FUL, or a SMAC.

276. Many of the payment bases utilized by State Medicaid programs do not utilize the AWPs and WACs published in the drug pricing compendia. For example, in order to receive reimbursement, providers must submit on each Medicaid claim a price referred to as the usual and customary charge ("U&C"). *See* 42 C.F.R. 447.331(b)(2) (payment bases include "[p]roviders' usual and customary charges to the general public"). Each State has its own definition for U&C,

and those definitions can materially vary from State-to-State. Some States define U&C as the price paid by retail or cash-paying customers. (*See, e.g.*, Tab 43, 11-18-08 J. Parker Dep. at 189-91 (U&C defined as the "price that a pharmacy would pay to a cash-paying customer"); Tab 54, 11-04-08 Tomlinson, II Dep. 373-74. However, other States have adopted "best price" or "most favored nation" definitions, which require the pharmacy to submit the lowest price charged or accepted from any customer or reimburser. (*See, e.g.*, Tab 29, 11-24-08 Hautea-Wimpee Dep. 308-10, 319-21; Tab 211, J. Dubberly Dep. Ex. 7, at VI-1; Tab 70, 12-3-08 J. Young Dep. at 202; *Massachusetts v. Mylan Labs, et al.*, 2008 WL 5650859, at *3 (D. Mass. Dec. 28, 2008); Tab 203, Roxane VA Ex. 10, at 72, 75, 77, 85) No State Medicaid program defines U&C on the basis of Roxane's AWPs or WACs. Dr. Duggan did not determine which of the Medicaid claims at issue were paid on the basis of U&C in all States. (Tab 19, 3-6-09 Duggan Dep. 289, 290-91).

United States' Response: Disputed. Virtually all States use EAC in a "lower of" methodology, and base EAC on AWP and/or WAC prices published by the compendia. (*See supra* United States Response to Paragraph 275; US-C-SF, ¶¶ 29-30) The United States does not dispute that state Medicaid programs also incorporate the usual and customary ("U&C") charge into their reimbursement formulae, and that states' definitions of U&C varied. Regarding the last sentence, the United States refers the Court to its Response to Paragraph 275 *supra*.

277. Rhode Island only pays Medicaid claims on the basis of the FUL or the U&C, if no WAC price was available in the drug pricing compendia. (Tab 70, 12-3-08 J. Young Dep. at 136-37.) From 1998 onwards, Roxane did not supply WAC prices to the drug pricing compendia for its generic drugs, including azathioprine, diclofenac sodium, furosemide, hydromorphone, ipratropium bromide, and sodium polystyrene sulfonate. (Tab 65, 5-11-07 Waterer Dep. 666-69) Removing claims for these NDCs after 1998Q1 reduces alleged damages from $258,983 to $53,147. (Tab 188, D. Williams Aff. ¶ 18.)

United States' Response: Disputed. Rhode Island paid Medicaid claims on the basis of an AWP + 15% formula when a published WAC was not available. (Fauci Exhibit 176 (12/4/2008 Avarista Dep.), at 222:1 - 224:5, 235:14 - 236:16) Further answering, although Roxane stopped reporting *new* WACs to pricing compendia for the referenced products in or around December 1997, Roxane's "last published" WACs continued to be published until late 1999. (US-BR-SF, ¶¶ 132-36)

278. Generic drugs often are subject to FULs, as well as the State maximum allowable cost ("State MAC") prices developed by State Medicaid programs. (*See, e.g.*, Tab 139, Ex. 139, DOJ Supp. Response to Interrogatory No. 7 at 9; Tab 204, *Generic Drug Cost Containment in Medicaid: Lessons from Five State Maximum Allowable Cost (MAC) Programs*, at 4 ("According to the National Pharmaceutical Council, 30 States had MAC lists in 2001; since then, a number of States have created new MAC lists")); Tab 205, *Medicaid Prescription Reimbursement Information by State – Quarter Ending March 2009* (45 State Medicaid programs have established MAC programs)) Except for New York, Dr. Duggan did not determine whether FUL prices applied to the Medicaid claims at issue. (Tab 19, 3-6-09 Duggan Dep. 289, 290-91)

United States' Response: Undisputed. Further answering, the United States refers to its Response to Paragraph 275 *supra.*

279. Many State Medicaid programs do not base their MAC prices on published prices. (*See, e.g.*, *California, ex rel. Ven-A-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc*., 478 F.Supp.2d 164, 180 (D. Mass 2007) (finding California MAIC program was not based on published benchmarks such as AWP or WAC); (Tab 68, 3-14-08 Wiberg Dep. 64-66) (Minnesota's MACs are based on actual acquisition costs provided by a group of pharmacies); (Tab 17, 12-15-08 Dubberly Dep. 67-68, 207; 306-307) (MACs determined by pharmacy benefit managers); (Tab 29, 11-24-08 Hautea-Wimpee Dep. 105-10) (Tab 206, AWP-IL-00025984) ("Generally, pharmacists in attendance seemed to understand the methodology used to establish State MAC rates [in Illinois], which is based upon actual acquisition costs obtained from providers.") (Tab 207, AWP-IL-00001108) (Tab 2, 12-10-08 Bridges Dep. 65, 244-251) (Tab 3, 12-11-08 Bridges Dep. 474-480) (Tab 47, 3-28-08 Sharp Dep. 62-66, 140, 250-51) (Tab 61, 3-26-08, J. Walsh Dep. 98) (Tab 25, 12-9-08 Fine Dep. 151-52, 201-204) (Tab 35, 3-25-08 Kenyon Dep. 37-40) (Tab 6, 12-2-08 Cheloha Dep. 128-132; 164-65) (Tab 13, 10-30-07 Collins Dep. 72-77) (Tab 208, DHCF Current Policy, Brand Medically Necessary and Medicaid Maximum Allowable Cost at 2) (Tab 209, Texas Health and Human Services Commission, Vendor Drug Program, Pharmacy Provider Handbook, March 1, 2006) (Tab 210, OIG Oct. 2003, "State Strategies to Contain Medicaid Drug Costs," at 13 (OEI-05-02-00680). Dr. Duggan did not determine whether MAC prices applied to any of the Medicaid claims at issue. (Tab 19, 3-6-09 Duggan Dep. 289, 290-91)

United States' Response: The United States does not dispute that some state Medicaid agencies do not set MACs based on published prices such as AWP and WAC. The paragraph is otherwise denied. Further answering, the United States refers to its Responses to Paragraphs 267 and 275.

E. The Calculation Of Alleged Damages Based On Actual State Medicaid Claims Data Within The Sixteen State Sample.

280. Dr. Duggan calculates alleged Medicaid damages for his Sixteen State Sample where State Medicaid Claims Data is available to him. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan

Report 30-93, Table 29) Dr. Duggan does not attempt to calculate damages on a claim-by-claim, State-by-State, basis. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 93-96)

United States' Response: The United States does not dispute the first sentence of this paragraph (except for the word "alleged"). The United States disputes the second sentence. For the "Sixteen State Sample," Dr. Duggan first examined the data to confirm that it was reliable and within the scope of this case. (Henderson Common Exhibit 41 (Duggan Decl.) ¶ 37) Dr. Duggan then examined a state's adjudication formula, and compared the formula to the actual claims data to see if he could verify that the amounts paid conformed to the formula. (*Id.*, ¶¶ 39-41) This process enabled Dr. Duggan to identify claims for which he was unable to replicate the amount paid, or where there appeared to be some other data error. Dr. Duggan excluded such claims from his analysis sample. (*Id.*) Finally, Dr. Duggan replaced alternative AWPs and/or WACs for each claim, to determine how use of the alternative prices would have affected state Medicaid spending. (*Id.,* ¶ 42) In effect, Dr. Duggan "re-adjudicated" each of the claims in the same manner as would have been done by the state had the alternative AWPs and/or WACs then been reported by Roxane. (*Id.*)

281. Dr. Duggan's calculation purportedly reflects the difference between the amounts actually paid by State Medicaid programs for the Medicaid Subject Drugs and the amounts that Dr. Duggan purports should have been paid, if the State Medicaid programs used his "Revised AWPs" or "Revised WACs" as a basis of payment. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 30-93)

United States' Response: Undisputed (except as to the word "purportedly").

282. Before Dr. Duggan calculates any alleged Medicaid damages, he limits the State Medicaid Claims Data to include only claims relating to the Medicaid Subject Drugs and the relevant periods. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 11, Tables 13A-29) Thus, Dr. Duggan does not include any Medicaid claims before February 15, 1999 for non-ipratropium bromide drugs, and pre-1996 for ipratropium bromide. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 11) Dr. Duggan also does not include any claims after October 1, 2001 for drugs that Roxane divested to Elan Pharma International Limited on September 28, 2001 (Roxanol (0054-

3751-44, 0054-3751-50, 0054-3751-58), Roxicodone (0054-4658-25, 0054-4665-25), Oramorph (0054-4805-19, 0054-4805-25, 0054-4805-27, 0054-4790-25, 0054-4792-25, 0054-4793-25)). (Tab 166, Duggan Rebuttal Report 19-20; *see also* Tab 166, First Am. Compl., Ex. A)

United States' Response: Undisputed.

283. Dr. Duggan also eliminates a number of invalid claims that appear in the State Medicaid Claims Data. For example, Dr. Duggan typically eliminates the following categories of claims, among others: (1) where the paid amount, billed amount, or quantity is less than or equal to 0; (2) where an amount paid by the State Medicaid program is greater than the amount billed by the healthcare provider (U&C); and (3) and where the dispensing fee in the claims data does not match the dispensing fees reflected in the Government's expert's surveys of purported State Medicaid reimbursement formulae. (Tab 188, D. Williams Aff. ¶ 4.).

United States' Response: Undisputed.

284. When analyzing the State Medicaid Claims Data, Dr. Duggan eliminates over 800,000 claims from his calculations of alleged Medicaid damages. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 30-92). For example, Dr. Duggan discards hundreds of thousands of claims because the paid amount exceeded the amount actually billed by the provider. With respect to Georgia, for instance, Dr. Duggan eliminates over 214,000 claims (56% of the total claims he analyzed in that State) because the amount paid on these claims exceeded the amount billed by the provider. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 65) Under Georgia's governing Medicaid regulations which utilized a "lower of" reimbursement methodology, the Medicaid payment on a drug claim should never have been greater than the provider's billed charge. (*See, e.g.*, Tabs 211-216, J. Dubberly 12-15-08 Dep. Exs. 7-12; Tab 217, HHC008-0012) Dr. Duggan also eliminates thousands of claims from his Medicaid difference calculations when the dispensing fee was inconsistent with the State Medicaid reimbursement policy. (*See, e.g.*, Tab 166, Duggan Ex. 001. 02-06-09 Duggan Report 80.) For example, when analyzing the State Medicaid Claims Data for Michigan, Dr. Duggan drops 22,314 claims "with an unsupported dispensing fee." (*Id.*)

United States' Response: Undisputed.

285. After dropping the various invalid claims described above, for the remaining claims Dr. Duggan calculates what the State Medicaid program purportedly would have paid on a particular claim if his "Revised AWPs" or "Revised WACs" had been utilized. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 9-11)

United States' Response: Undisputed (except as to the word "purportedly").

286. To determine what a State Medicaid program purportedly would have paid on a Medicaid claim, Dr. Duggan first adds a twenty-five percent markup to his "Revised WAC," if the State utilizes "AWP" in its definition of Estimated Acquisition Cost ("EAC"). (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 10) If the State utilizes WAC, however, Dr. Duggan does not

add a twenty-five percent markup to his "Revised WAC." (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 41-42) Next, Dr. Duggan inputs the "Revised AWP" (or "Revised WAC") into the State's EAC formula. (*See e.g.*, Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 31-32) Dr. Duggan inserts his "Revised AWP" (or WAC) into the State reimbursement formula to arrive at an adjusted payment amount, which he uses as the basis for his alleged damages calculation. (*Id.*)

United States' Response: Undisputed (except as to the word "purportedly").

F. Intrastate Extrapolations To CMS Datasets Within The Sixteen State Sample To Estimate Alleged Damages.

287. Within the Sixteen State Sample, there are a number of quarters where State Medicaid Claims Data is lacking or incomplete. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report Table 29) In fact, Dr. Duggan does not possess complete State Medicaid Claims Data for any of the States within the Sixteen State Sample. (*Id.*)

United States' Response: Undisputed. The United States further notes that the sixteen states for which Dr. Duggan did have state claims data account for 68 percent of all claims for Roxane's Complaint products, and thus form a strong foundation for his extrapolation to States for which he used SDUD and SMRF/MAX data. (Henderson Common Exhibit 41 (Duggan Decl.), ¶ 17)

288. Because Dr. Duggan does not possess complete State Medicaid Claims Data for any State within his Sixteen State Sample, he cannot calculate "damages" on a claim-by-claim basis for every quarter for each of the Medicaid Subject Drugs. Instead, Dr. Duggan performs an intrastate extrapolation (utilizing one of the other CMS Datasets) to estimate alleged damages for those quarters where State Medicaid Claims Data is lacking. (*See e.g.,* Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 30-93, Table 29)

United States' Response: Undisputed.

289. In particular, Dr. Duggan lacks State Medicaid Claims Data for the following quarters: California (2007Q4 through 2008Q1); Florida (2006Q1-2008Q1); New York (2007Q3-2008Q1); Pennsylvania (1996Q3-1998Q2 and 2007Q2-2008Q1); Missouri (1996Q3-1997Q4); Illinois (2007Q1-2008Q1); Massachusetts (2008Q1); Texas (2006Q1-2008Q1); Georgia (1996Q3-2000Q3 and 2007Q1-2007Q4); North Carolina (1999Q1-2000Q4) and (1996Q3-1998Q4), (2007Q2-2008Q4); New Jersey (2007Q1-2008Q1); Michigan (1996Q3-2000Q3 and 2007Q3-2008Q1); Louisiana (2002Q1-2002Q2 and 2007Q4-2008Q1); Kentucky (2005Q2-2008Q1); Wisconsin (2006Q1-2008Q1) and Virginia (2007Q1-2008Q1). (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report Table 29) Dr. Duggan applies an intrastate extrapolation for each NDC and in each quarter during the relevant period for which he lacks State Medicaid Claims Data. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report Table 29)

United States' Response: To the extent the above recitation accurately describes Table 29 in Dr. Duggan's report, the United States does not dispute it.

290. Dr. Duggan applies an intrastate extrapolation to one of the four different CMS Datasets. (*Id.*) This intrastate extrapolation is based only on State Medicaid Claims Data from the actual State in which such data is missing. For example, Dr. Duggan does not perform an intrastate extrapolation to a quarter where he lacks State Medicaid Claims Data in Virginia using data related to the payment of Kentucky Medicaid claims.

United States' Response: Undisputed.

G. Interstate Extrapolations To CMS Datasets For The Remaining Thirty-Three State Medicaid Programs To Estimate Alleged Damages.

291. Dr. Duggan uses an interstate extrapolation to estimate "damages" for the remaining thirty-three State Medicaid programs in which he does not utilize State Medicaid Claims Data. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 93-96) In particular, Dr. Duggan applies an interstate extrapolation for each NDC and in each quarter during the relevant period for the thirty-three State Medicaid programs that are not included in the Sixteen State Sample. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 93-96, Tables 31A-B) Thus, none of the damages Dr. Duggan estimates for these thirty-three State Medicaid programs is based on a claim-by-claim determination. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 93-96; *see also* Tab 218, *Questions by Chairman Tom Coburn for Daniel R. Levinson, Inspector General,* U.S. Department of Health and Human Services (April 28, 2006), available at http://coburn.senate.gov/oversight/index.cfm`FuseAction=Hearings.Home&ContentRecord_id=47a389df-7e9c-9af9-765c-d9f650ad0d43&Issue_id=

United States' Response: Undisputed, except that the reference to Tab 218 makes no sense.

292. Similar to intrastate extrapolation, Dr. Duggan applies an interstate extrapolation to one of the four different CMS Datasets. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 93-69) As part of his interstate extrapolation, Dr. Duggan identifies for each NDC and quarter, the number of States within the Sixteen State Sample in which he possesses State Medicaid Claims. (Tab 166, Duggan Ex. 001, 02-06-09 Duggan Report 94). In some NDC-quarters Dr. Duggan has State Medicaid Claims Data for far fewer than all of the States comprising the Sixteen State Sample. (Tab 188, D. Williams Aff. ¶ 17.) For example in 2007Q4 for NDC 0054-4297-31, only two States within the Sixteen State Sample have State Medicaid Claims Data. (*Id.*) For this NDC and in this quarter, Dr. Duggan utilizes State Medicaid Claims Data from just two States to extrapolate to thirty-three other State Medicaid programs. (*Id.*)

United States' Response: Undisputed. However, the United States notes that Dr. Duggan used State Medicaid claims data for 93.5 percent of the 7.979 million claims for these 16 states, while he

used SMRF/MAX/MSIS claims data for 4.3 percent, and aggregate SDUD data for an additional 2.3 percent. (Tab 219, at 16)

Within the "Sixteen State Sample," it is true that for some NDC-quarters Dr. Duggan does not have access to state-level claims data for all 16 states. One of Roxane's proffered experts (Dr. Williams) notes that in the fourth quarter of 2007 for Roxane NDC 00054-4297-31 Dr. Duggan utilizes state claims data from two states to extrapolate to 33 other state Medicaid programs. Dr. Williams leaves out some important information, however. First, he fails to explain that only 18 of the 33 states show *any* utilization at all for that NDC during that quarter, or that total utilization for all states was only $10,177. Second, Dr. Williams fails to note that the total utilization for the NDC in question for the two states *with* claims data was $4,465, while the total utilization for the other states combined was $5,712. Thus, the basis for the extrapolation represented almost 45% of the total utilization.

293. Unlike intrastate extrapolation, however, Dr. Duggan's interstate extrapolation is based on State Medicaid Claims Data from different State Medicaid programs. In other words, by way of example, for NDC 0054-4297-31 in the third quarter of 2007, Dr. Duggan performs an interstate extrapolation to estimate damages in Rhode Island by relying on data related to the payment of claims in the California, Louisiana, Massachusetts and Missouri State Medicaid programs.

United States' Response: The United States objects to the statement because it is unsupported by any reference or evidence. As such, the statement violates LR 56.1. Accordingly, the United States declines to respond.

H. The Total Amount Of Alleged Medicaid Damages Based On Interstate And Intrastate Extrapolations To CMS Datasets.

294. Dr. Duggan calculates over $3.5 million in alleged Medicaid damages based on the intrastate extrapolations he performs within his Sixteen State Sample. (Roxane Tab 219, Duggan Ex 007, Duggan Rebuttal Report, Table 29 Revised)

United States' Response: The United States does not dispute the statement to the extent that the sum of the figures in the "Federal DIFF" column which correspond to the rows entitled "SDUD" and "SMRF-MAX" total over $3.5 million. Otherwise, the statement is disputed.

295. Dr. Duggan calculates an additional $20.3 million in alleged Medicaid damages based on the interstate extrapolation he performs for the other 33 State Medicaid programs that are not included in the Sixteen State Sample. (*Id.*)

United States' Response: Undisputed.

296. Overall, Dr. Duggan calculates over $23.8 million in alleged Medicaid damages based upon intrastate and interstate extrapolations to CMS Datasets. (*Id.*)

United States' Response: Undisputed, subject to the response to No. 294.

I. Total Alleged Medicaid and Medicare Damages Post-December 31, 2000.

297. Dr. Duggan calculates alleged damages for Medicaid and Medicare claims submitted for payment post-December 31, 2000. (Tab 188, D. Williams Aff. ¶ 8.). When claims paid after December 31, 2000 are excluded from the alleged damages calculation, Dr. Duggan's Medicaid damages are reduced by $43.3 million and his Medicare damages are reduced by almost $47 million in his Roxane only scenario (Novaplus excluded) and by over $732 million in his Roxane and Dey scenario (Novaplus excluded) (*Id*.)

United States' Response: The United States does not dispute that Dr. Duggan calculates damages post-December 31, 2000. Further answering, the United States notes that Roxane has offered no evidence to support a finding that damages should be cut off at December 31, 2000, or any other date. The United States also admits that if Dr. Duggan did not calculate damages post-December 31, 2000, the damages amounts would be smaller, though not necessarily by the amounts cited in this paragraph.

DATED July 24, 2009

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ James J. Fauci
JAMES J. FAUCI

Dated: July 24, 2009